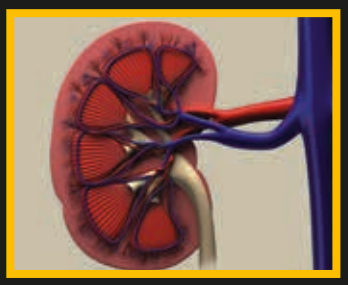
NEW JERSEY AIDSLine

December 2013

Published by FXB Center, School of Nursing, Rutgers, The State University of New Jersey

CE Continuing Education



CME/CE Article #1

CME/CE Article #2

News

The New Jersey Response to Heroin Use and the Abuse and Misuse of Prescription Drugs

Sindy M. Paul, MD, MPH, FACPM

The abuse and misuse of prescription drugs has emerged as a public health crisis in New Jersey. The number of drug treatment admissions for opioid pill addictions in this state tripled from 2006 to 2011, with more than 8,600 admissions in 2011. Nearly half of these patients were age 25 or younger.[1] In 2010, New Jersey had 7,238 admissions to State-licensed or certified substance abuse treatment programs as a result of prescription painkiller abuse. This is an increase of nearly 2,000 from the previous year's admissions, and an increase of more than 5,000 from 2005.[2] Prescription drug abuse related mortality increased by 51% in New Jersey from 6.5/100,000 population in 1999 to 9.8/100,000 population in 2010.[3]

The epidemic of prescription drug abuse has triggered a resurgence in heroin abuse by young people. Heroin is a less expensive analogue of prescription pain killers that delivers a stronger high and is currently more readily available than ever in areas with suburban and rural zip codes.[1] Drug treatment facilities in New Jersey are seeing record numbers of admissions for heroin. Mirroring the increase in admissions for opioid pill addictions: from 2006 to 2011, heroin addiction admissions to New Jersey treatment facilities jumped by nearly one-third for those under age 25, with more than 6,600 during 2011 alone.[1]

Drug abuse, including the abuse of heroin, has been associated with the HIV epidemic in New Jersey since the first cases of AIDS were reported in the early 1980s. As of the most recent report (December 31, 2012), injection drug use accounted for 35% of the 77,828 cumulative reported HIV or AIDS cases in New Jersey and 20% of those currently living with HIV or AIDS.[4] In addition to its association with HIV, heroin abuse can cause other serious health conditions, including fatal overdose, spontaneous abortion, infection of the heart lining and valves, liver or kidney disease, pulmonary complications, as well as infectious diseases such as hepatitis.[5]

The national picture

Nationally, the Centers for Disease Control and Prevention (CDC) identified prescription pill abuse as the fastest growing drug problem in the United States. The major increase is in unintentional drug overdose from opioid analgesics, which have caused more overdose related deaths since 2003 than cocaine and heroin combined. The CDC reports that for every unintentional opioid analgesic death, there are:

- 461 reported nonmedical uses of opioid analgesics
- 161 reports of drug abuse or dependence
- 35 emergency department visits, and
- 9 people admitted for substance abuse treatment

Nonmedical use is defined as opioid analgesic use without a prescription or a medical need to take an opioid analgesic.[6] Misuse and abuse of prescription painkillers is expensive: costing the United States an estimated $53.4 billion a year in lost productivity, medical costs and criminal justice costs.[3] The two major at risk populations in the United States are the estimated 9 million persons who report long-term medical use of opioids, and the approximately 5 million persons who report nonmedical use in the past month.[7]

Prescribing and abuse

Prescribing practices play an important role in opioid analgesic abuse:

- The overwhelming majority, 80%, of patients on these medications receive low dose (<100 mg morphine equivalent dose per day) prescriptions from a single health care provider.[8,9] These patients account for 20% of the overdoses.
- 10% of patients receive prescriptions for high doses (≥100 mg morphine equivalent dose

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Published by the FXB Center, School of Nursing, Rutgers, The State University of New Jersey and the New Jersey Department of Health, Division of HIV, STD and TB Services

NJ Health New Jersey Department of Health

Editor's column

By Virginia Allread, New Jersey AIDSLine Editor

In researching "Injecting Drug Use Trends in New Jersey", the second continuing education article in this issue of AIDSLine, I realized that not only had the demographics of injecting drug use changed over the past three decades from inner city, ethnic minority to suburban or rural, but that in 2012 an injecting drug user was 13 times more likely to die of a drug overdose than to acquire HIV. During the four months we were working on the article, both my co-author Sarah and I experienced the untimely passing of someone known to us because of a drug overdose. As we were making the final edits, the son of my husband's colleague died of an overdose. One of the field testers shared a similar, personal story.

Whether urban, suburban or rural, this decade's lost lives to overdose are as painful as the lives lost to injecting drug use-associated HIV in the '80s. Although the current epidemic of injecting drug use has seen a decrease in the level of HIV transmission, we owe it to those who died during the 1980s to ensure that the young people now abusing prescription or illegal drugs avoid HIV and hepatitis C until they are ready and able to recover. Hopefully this time around, we've learned from our mistakes. With continued support for syringe access programs and legalized over-the-counter sale of syringes, public health professionals can continue their proactive efforts to prevent the negative impacts of injecting drug use — including HIV and hepatitis — while exploring new ways to prevent drug abuse in the first place. ❖

per day) from a single prescriber. These patients are involved in 40% of the opioid overdoses.[10,11]

- The remaining 10% of patients get high daily dose prescriptions from multiple prescribers and account for 40% of the opioid overdoses and are likely diverting these medications to people who use them without a prescription.[12]
- Among nonmedical users, 76% take medication prescribed for someone else and only 20% indicate they received the medication through a prescription from their physician.[13]

New Jersey's response

The most recent Trust for America's Health report ranks New Jersey as the 11th lowest drug overdose death rate in the United States. The report ranked states according to their proactive and effective strategies for addressing prescription drug abuse. New Jersey received seven on a scale of 10 possible points, ranking it 18th in the country. New Jersey received two points for having a Good Samaritan law (officially the Overdose Protection Act) providing legal protection for those who call 911 in an overdose situation, and a law expanding access to naloxone, the antidote to opioid overdoses.[3] New Jersey also received points for having a physician monitoring program, supporting substance abuse treatment, requiring a physician-patient relationship, having a pharmacy lock-in program, and prohibiting patients from withholding information from prescribers.

The three areas in which New Jersey did not receive points are:

- New Jersey's physician monitoring program is voluntary for prescribers, Trust for America would prefer that it is mandatory
- New Jersey does not require or recommend continuing medical education on the topic
- New Jersey does not require pharmacists to check an ID before dispensing controlled dangerous substances (CDS)[3]

The rest of this article describes New Jersey's approach to prescription pill abuse, including the seven areas for which New Jersey received points in the Trust for America's Health Report.

1. Prescription Monitoring Program: Nationally, prescription monitoring programs were created through funding from Congress through the Fiscal Year 2002 United States, Department of Justice Appropriations Act (Public Law 107-77). Their purpose is to help prevent and detect the diversion and abuse of pharmaceutical controlled substances by enhancing the ability of regulatory and law enforcement agencies to collect and analyze controlled substance prescription data. Prescription monitoring programs focus on the retail level, where prescribed medications are purchased.[14]

The New Jersey Prescription Monitoring Program (NJPMP), established by New Jersey law (N.J.S.A. 45:1-45 et. seq.), is a statewide database for the collection of prescription data on CDS and human growth hormone (HGH) dispensed in outpatient settings in New Jersey, and by out-of-state pharmacies dispensing into New Jersey. Pharmacies are required to submit this data at least twice per month but physician participation is voluntary.[15]

NJPMP access is granted to prescribers and pharmacists who are licensed by the state of New Jersey and in good standing with their respective licensing boards. Prior to prescribing or dispensing a medication, qualified prescribers and pharmacists registered to use the NJPMP are able to access the website and request the CDS and HGH prescription history of the patient. Users must certify before each search that they are seeking data solely for the purpose of providing healthcare to a specific, current patient. Authorized users agree that they will not provide access to the NJPMP to any other individuals, including members of their staff. The patient information is strictly confidential, in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules.[15]

Prescribers or pharmacists who access or disclose NJPMP information for any purpose other than to provide healthcare to a current patient or to verify the record of prescriptions issued by the prescriber, are subject to civil penalties of up to $10,000 for each offense and disciplinary action by the prescriber's or pharmacist's professional licensing board. The same penalties apply if a prescriber or pharmacist allows another individual to access the NJPMP using his/her access codes.[15]

As with all prescription monitoring programs, patient information in the NJPMP is intended

The New Jersey Response to Heroin Use and Abuse and Misuse of Prescription Drugs

Governor Chris Christie signs the bipartisan Overdose Protection Act (S2082) into law at Turning Point in Paterson, N.J. on Thursday, May 2, 2013. (Governor's Office/Tim Larsen)

to supplement an evaluation of a patient, confirm a patient's prescription history, or document compliance with a therapeutic regimen. When prescribers or pharmacists identify a patient as potentially having an issue of concern regarding drug use, they are encouraged to help the patient locate assistance and take any other action deemed appropriate.[15]

Although prescription monitoring programs, such as NJPMP, are state-based, information sharing among states is a national priority. The Bureau of Justice Assistance has developed policy and technology to enable interstate sharing of the information in this program.[16]

2. Project Medicine Drop: New Jersey also provides consumers with a way to dispose of unused medications, and to keep medications safe within their homes. Project Medicine Drop allows consumers to dispose of unused and expired medications anonymously, seven days a week, 365 days a year, at "prescription drug drop boxes" located within the headquarters of participating police departments in each of the 21 counties in New Jersey. The participating police agencies maintain custody of the deposited drugs, and dispose of them according to their normal procedures for the custody and destruction of controlled dangerous substances. One-day events are also available statewide through the U.S. Drug Enforcement Administration's National Take Back Initiative and the American Medicine Chest Challenge, which is sponsored in New Jersey by the U.S. Drug Enforcement Administration (DEA), Partnership for a Drug Free New Jersey, and Sheriffs' Association of New Jersey. Both Project Medicine Drop and the American Medicine Chest Challenge (described next) provide single-day opportunities to drop off unused medications at pre-identified, secure locations.[17]

3. The American Medicine Chest Challenge: The American Medicine Chest Challenge raises awareness about the adverse consequences of prescription drugs. It includes an annual nationwide day of disposal, the second Saturday of November, when unused, unwanted, and expired medicine can be taken to a collection site or collected from the home for proper disposal. It is a partnership between community based public health organizations with law enforcement.[18]

4. The National Prescription Drug Take-Back Day: The National Prescription Drug Take-Back Day is an annual event that provides a safe, convenient, and responsible means of disposing of prescription drugs. Like the American Medical Chest Challenge, it also provides education on the dangers and potential abuse of prescription drug use.[19]

5. Education campaigns: Education is an important component of the New Jersey response. "The Right Prescription for New Jersey," is an educational campaign for the public during which the State of New Jersey Commission on Investigation (SCI), along with the DEA, the Partnership for a Drug-Free New Jersey and other entities, produced multi-media advertisements, including a radio message from a New Jersey woman who lost her son to a prescription-pill overdose.[1] A medical education campaign has also been implemented with presentations at medical organizations and continuing medical education presentations to prescribers.

6. Good Samaritan law: New Jersey is now the 12th state to enact protections for "Good Samaritans" in drug overdose cases. The Overdose Protection Act allows people to call 911 when a friend or neighbor is overdosing and they will not be liable for drug use or possession charges for calling the police. The Act also provides Good Samaritan protection for anyone administering an opioid antidote to an overdose victim. Now medics and even average citizens in New Jersey can use these opioid antidotes to aid overdose victims without fear of being sued.[20]

7. Drug treatment expansion and Medicaid lock in program: New Jersey is also addressing prescription drug abuse from the treatment perspective. Medicaid expansion will provide expanded access to substance abuse treatment and services. Medicaid also has a lock in program in which recipients suspected of misusing CDS are locked into using a single pharmacy and a prescriber. Physicians are required to have a bona fide doctor-patient relationship with persons to whom the CDS is prescribed. This includes a history, physical examination, assessment, and plan.[3]

Prescription drug abuse is an increasing public health problem. New Jersey has been nationally acclaimed for its pro-active approach in addressing this epidemic. ❖

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background photo: Governor Chris Christie, Jon Bon Jovi and Turning Point CEO Dr. Manuel Guantez talks with patients prior to signing the bipartisan Overdose Protection Act (S2082) into law at Turning Point in Paterson, N.J. on Thursday, May 2, 2013. (Governor's Office/Tim Larsen)

CE CONTINUING EDUCATION

The Kidney in HIV-1

Release Date: December 1, 2013 • Expiration Date: November 30, 2015 • Course Code: 16HH01 • Nursing credit for this activity will be provided through November 30, 2015

SPONSOR

Sponsored by François-Xavier Bagnoud Center, School of Nursing, Rutgers, The State University of New Jersey and the Center for Continuing and Outreach Education at Rutgers Biomedical and Health Sciences.

FUNDING

This activity is supported by an educational grant from the New Jersey Department of Health (NJDOH)—Division of HIV, STD and TB Services, through an MOA titled "Education and Training for Physicians and other Healthcare Professionals in the Diagnosis and Treatment of HIV/AIDS."

STATEMENT OF NEED

Individuals with HIV-1 infection are inherently prone to unique factors and exposures increasing their risk for kidney disease. In part because traditional risk factors for chronic kidney disease (CKD) such as diabetes, hypertension, and dyslipidemia are more common HIV-1 infected individuals particularly with ART exposure. When tackling kidney disease in this population, one must consider a broader array of potential diagnoses. Kidney disease in HIV-1 infected patients encompasses an array of disorders that includes acute kidney injury (AKI), glomerular disorders, CKD, and drug induced injuries in its toxic or allergic forms.

There is strong evidence linking AKI, proteinuria, and CKD with adverse outcomes among HIV-1 infected individuals. Conversely, the incidence of all-cause mortality, end stage renal disease, cardiovascular disease, and heart failure increases incrementally with the severity of AKI. To exacerbate the situation, late diagnosis is common: the vast majority of kidney disease is asymptomatic and thus requires markers for both screening and diagnosis.

Among antiretroviral agents currently approved for the treatment of HIV-1, CKD has been most clearly established with nucleoside reverse transcriptase inhibitor: tenofovir particularly when used with ritonavir boosting; and protease inhibitors: indinavir, atazanavir, and to lesser extent lopinavir/ritonavir. Whether on ART or not, clinicians who treat HIV populations should screen for renal function.

TARGET AUDIENCE

This activity is designed for physicians, nurses, social workers, health educators, and other health care professionals in New Jersey who are involved in the care of people with HIV.

METHOD OF PARTICIPATION

Participants should read the learning objectives, review the activity in its entirety, and then complete the self-assessment test, which consists of a series of multiple-choice questions. Upon completing this activity as designed and achieving a passing score of 70% or more on the self-assessment test; participants will receive a letter of credit and the test answer key four (4) weeks after receipt of the self-assessment test, registration, and evaluation materials. This activity may also be completed online at ***http://ccoe.rbhs.rutgers.edu/catalog/***.

Estimated time to complete this activity as designed is 1.06 hours for nurses, and 0.75 hour for physicians.

LEARNING OBJECTIVES

Upon completion of this activity, participants should be able to:

1. List the indicators of renal injury in HIV infected patients
2. Recognize the array of kidney disorders in HIV infected patients
3. Describe the management of kidney disease in HIV infected individuals

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CME

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DISCLOSURE DECLARATIONS

Mohamed G. Atta is supported by the National Institute of Diabetes and Digestive and Kidney Diseases grant P01DK056492; he works as a consultant for Gilead and GSK. In addition he is a Scientific Advisory Board Member for both Merck and BMS.

The activity directors, planning committee members, peer reviewer and field testers have no relevant financial relationships to disclose.

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NEW JERSEY AIDSLine December 2013

The Kidney in HIV-1

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Learning objectives:

By the end of this activity participants should be able to:

1. List the indicators of renal injury in HIV infected patients
2. Recognize the array of kidney disorders in HIV infected patients
3. Describe the management of kidney disease in HIV infected individuals

Introduction

The epidemiology of kidney disease in HIV-1 infected individuals has been transformed over the years driven by multiple dynamic forces including genetic susceptibility, race, age, comorbid conditions (diabetes, hypertension, and co-infection with hepatitis) and access to antiretroviral therapy (ART). Consequently, in HIV-1 infected individuals lacking access to ART, kidney disease is largely driven by patient genetics, demographics, and HIV-1 infection itself. Conversely, in settings where ART is accessible, kidney disease is rather driven by non-HIV-1 related causes similar to those affecting the general population. In addition to the kidney diseases affecting the general population, those with HIV-1 infection are inherently prone to unique factors and exposures increasing their risk for kidney disease. Thus, when tackling kidney disease in this population, one must consider a broader array of potential diagnoses. Preventive measures and management can ultimately be implemented by recognizing the varied demographics, risk factors, clinical presentations of kidney disease, and access to treatment in this population.

Inset photo: Histopathology of HIVAN, courtesy of Dr. S. Bagnsco and Dr. M. Atta, The Johns Hopkins University School of Medicine

Release Date: December 1, 2013 • Expiration Date: November 30, 2015 • Course Code: 16HH01 • Nursing credit for this activity will be provided through November 30, 2015

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NJ Health New Jersey Department of Health

Rutgers François-Xavier Bagnoud Center SCHOOL OF NURSING

Indicators of kidney disease in HIV-1 infected patients

The vast majority of kidney disease is asymptomatic and thus requires markers for both screening and diagnosis. Unfortunately, no renal specific marker exists and most screening tools are primarily centered on surrogate markers such as serum creatinine, creatinine based equations, and assessment of proteinuria. As serum creatinine is significantly influenced by weight, age, race, and gender, there is essentially no standardized estimation of kidney function among individuals. In addition, serum creatinine is not only ultra-filtered by the glomerulus but is also excreted through proximal tubular cells.[1] As renal function declines, tubular secretion of creatinine is increased making reliance on serum creatinine erroneous. Creatinine secretion is also inhibited by a number of drugs including antiretroviral agents generating imprecision of renal function estimations particularly in patients with underlying kidney disease. Although kidney biopsy offers a definitive diagnosis and is safe to perform in HIV-1 infected individuals,[2] it is not widely utilized.

For disease screening, the use of the serum creatinine with one of the estimating formulas (Table 1) to assess function and evaluate for proteinuria is advocated. Although the least accurate, the Cockcroft-Gault formula that measures creatinine clearance, remains the formula used by the FDA and pharmaceutical industry for drug dosing. The recently introduced cystatin C based equation or hybrid equations that incorporate both serum cystatin C and serum creatinine[3] are not recommended in HIV-1 infected individuals. The CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration) equation appears the most accurate compared to all other equations in the HIV-1 infected population. Because proteinuria is the hallmark of glomerular disease in particular, and may be the earliest indicator of kidney disease in some patients, its assessment is essential. A random protein-to-creatinine ratio on a single urine sample (also known as a "spot" urine protein-to-creatinine ratio) has been shown to be an accurate measure of proteinuria. Urine dipstick is widely employed for proteinuria screening and although considered effective, the use of a quantitative test is likely to provide a more accurate assessment allowing identification of kidney disease in more patients.[4]

Other potential biomarkers of kidney injury: Finally, several serum and urinary renal biomarkers offer screening and diagnostic advantage in the detection of proximal tubular injury particularly in the setting of potential drug nephrotoxicity. Clinically available markers include serum phosphorus, uric acid, bicarbonate, potassium, and urinary fractional excretion of phosphorus or uric acid. Additionally, the presence of urine glucose in non-diabetics or controlled diabetic patients is an indication of renal proximal injury. These biomarkers offer better monitoring mechanism and earlier detection of kidney damage compared to serum creatinine or estimating equations. Application of these biomarkers is suggested in patients at risk for renal proximal tubular injury. The following patients may be at risk for future renal proximal tubular injury: patients on tenofovir-based ART regimens, specially those patients with a history of kidney disease and patients with low body mass index (particularly women, Caucasians and Asians).

HIVAN is the most aggressive renal disorder in this population and occurs almost exclusively in individuals of African descent.

Renal disorders in HIV-1

Kidney disease in HIV-1 infected patients encompasses an array of disorders that includes acute kidney injury (AKI), glomerular disorders, chronic kidney disease (CKD), and drug induced injuries in its toxic or allergic forms. Once kidney disease is identified, it is important to assess its acuity and to distinguish between HIV-1 and non–HIV-1 related causes. By definition, AKI is an abrupt decline in renal function that is reversible in most cases. On the other hand, CKD is a reduction (sometimes progressive) in renal function that is largely irreversible. These may be difficult to distinguish if no baseline data are available. Standardized definitions of AKI and CKD are now available, which is helpful for practice, research, and public health:

- AKI is defined as an increase in serum creatinine by ≥0.3 mg/dl (≥26.5 µmol/l) within 48 hours, or ≥1.5 times baseline (when known), or urine volume <0.5ml/kg/h for 6 hours.[5]
- CKD is defined as the presence for more than 3 months of an estimated GFR of < 60 ml/min or kidney damage (presence of proteinuria or abnormalities on ultrasound) with or without decrease eGFR.[6]

A differential diagnosis can be established based on clinical and laboratory data, but definitive diagnosis is only possible through kidney biopsy.

Acute kidney injury

HIV-1 infected individuals are at high risk for AKI. Various etiologies may result in this broader syndrome including extra-renal pathology (hemodynamic renal failure due to heart failure, pancreatitis, hepatic cirrhosis or renal outflow obstruction), specific renal parenchymal diseases (allergic interstitial nephritis, acute glomerular, or vasculitic disorders), or non-specific disorders (ischemic or toxic injury). The incidence of community acquired AKI has been estimated to be 5.9 per 100 person-years.[7] Acute allergic interstitial nephritis (AIN) is a common cause of AKI in HIV-1 infected individuals and was the third most common finding (11%) on kidney biopsy in 262 selected HIV-1 infected individuals with renal dysfunction requiring diagnostic biopsy.[8] The great majority of AIN cases were due to non-steroidal anti-inflammatory drugs and sulfamethoxazole/trimethoprim while antiretroviral medications were less likely to be implicated.[8] Thus, it is imperative to consider this diagnosis in any HIV-1 patient with AKI where the diagnosis is not readily evident.

Among hospitalized patients, approximately 18% of HIV-1 infected patients develop AKI with nearly a 3-fold higher risk compared to HIV-1 uninfected patients.[9] Risk factors for AKI include pre-existing hypertension, diabetes, underlying kidney disease, liver disease, low CD4 cell counts, and high HIV-1 RNA levels.[9] Patients who develop AKI during their hospitalization often have acute tubular injury, AIN, urinary obstruction, or drug-related nephrotoxicity. Therefore a careful review of a patient's history and recent exposures are vital to inform appropriate further work-up and management of AKI. Additional work-up for AKI include:

- Assessing the pace of serum creatinine rise
- Examining urinary sediment for clues to the diagnosis such as drug crystals,

- Obtaining renal sonogram,
- And ultimately kidney biopsy if the diagnosis is not readily evident.

It is important to note that HIV-1 associated nephropathy (HIVAN) must be considered and diagnosed quickly in HIV-1 infected individuals with AKI, due to its poor prognosis if untreated. Drug-related toxicities are common in the HIV-1 infected population and include:

- AKI and/or tubular disorders (e.g., with tenofovir),
- AIN, and crystalluria or renal stones mainly due to indinavir and to a lesser extent with atazanavir.

In addition, hepatitis C-related membranoproliferative glomerulonephritis and rhabdomyolysis due to illicit drug use, statin drug interactions or, rarely, associated with primary HIV-1 infection should be considered in HIV-1 infected patients.[10,11]

No special precautions are required for HIV-1 infected individuals on maintenance dialysis and no necessity to assign a dedicated nurse or an isolated chair to those patients while on hemodialysis.

Glomerular disorders: These disorders may be directly mediated by HIV-1, such as in HIVAN, HIV-1 associated immune complex (HIVICK), or thrombotic microangiopathy (TMA); unrelated to HIV-1 infection, such as diabetes, hepatitis C co-infection, intravenous drug use, or primary disorders such as classic focal segmental glomerulosclerosis and amyloidosis.

HIV-1 associated nephropathy

HIVAN is the most aggressive renal disorder in this population and occurs almost exclusively in individuals of African descent.[12] In the pre-ART era, the prevalence rates ranged from 1–15% in autopsy studies.[13,14] In those treated before widespread use of ART, most cases of CKD were attributed to HIVAN in at risk population,[15] but in subsequent years with viral suppression, non-HIVAN related kidney disorders predominates.[16] The exclusiveness of HIVAN to patients of African descent appears driven by sequence variants in the apolipoprotein L1 (APOL1) gene encode.[17] However, not all HIV-1 infected patients of African descent carrying these risk variants develop HIVAN and a number of HIVAN patients do not carry these risk variants.[18] This suggests that this disorder may also be facilitated by interactions of host genetic susceptibility, environmental factors, viral factors, or yet other functional genetic variants such as the one recently discovered and identified in the APOL1 gene.[19]

Untreated HIVAN presents with high serum creatinine levels with nephrotic range (>3 g/24h) proteinuria and inevitable progression to end stage renal disease (ESRD).[20] Nephrotic range proteinuria, low CD4 count, and high viral load have not been shown to be sufficiently predictive of HIVAN.[16,20] Renal sonogram findings also have limited predictive value.[21] Hypertension is unusual in patients with HIVAN and one study noted that 43% with biopsy proven disease did not have hypertension.[22]

The unique histopathology allows definitive diagnosis of HIVAN, which is essential as renal function deteriorates rapidly and untreated patients will progress to ESRD within weeks to months. Treatment consists of primarily ART along with adjunctive therapy that includes angiotensin converting enzyme inhibitors/angiotensin receptor blockers, and glucocorticoids.[12] Retrospective analyses strongly suggest that ART improves dialysis-free survival in patients with HIVAN.[23]

HIV-1 associated immune complex diseases

These diseases comprise a spectrum ranging from post-infectious to "lupus-like" glomerulonephritis and is referred to as HIVICK.[24] In contrast to HIVAN, HIVICK does not have a strong racial predilection. Clinically, these patients have less aggressive disease with subnephrotic range proteinuria of approximately 1 gram/24h and milder kidney dysfunction compared to patients with HIVAN.[24] As with HIVAN, biopsy is required for definitive diagnosis. Combined ART use was not associated with decreased odds of HIVICK but these patients are less likely to progress to ESRD compared to those with HIVAN.[24]

HIV-1 associated thrombotic microangiopathy

This syndrome comprises a broader range of diseases that include:

- Diarrhea-associated hemolytic uremic syndrome (dHUS)
- Atypical HUS (aHUS), and
- Thrombotic thrombocytopenic purpura (TTP)

These entities are triggered by endothelial cell injury with subsequent release of platelet-aggregating substances resulting in the formation of thrombotic lesions in terminal arterioles and capillaries. In TTP, patients lack the protease a-disintegrin-like and metalloprotease and thrombospondin repeats that normally cleaves ultra-large von Willebrand factor (vWF) multimers.[25] This deficiency results in unregulated accumulation of multimeric vWF, which results in platelet aggregation and thrombosis.[26] The majority of patients with HIV-1 infection who develop TTP have severe deficiency of this vWF-cleaving protease a-disintegrin-like and metalloprotease and thrombospondin (ADAMT13) repeats similar to non-HIV-1 patients with TTP.[27] Clinically, TTP in HIV-1 patients typically occurs in those who are severely immune-compromised and is associated with consumptive thrombocytopenia and microangiopathic hemolytic anemia in addition to significant AKI and variable degree of proteinuria that can be nephrotic.[28] In HIV-1 patients with TMA due to ADAMT13 deficiency, plasma exchange is the treatment of choice as it may be effective in reversing both the hematological and, to a great degree, the renal manifestations of TMA. It is important to note that the use of ART has minimized the incidence of this syndrome. [27]

Chronic kidney disease

CKD develops as a result of both HIV-1 related risk factors and more traditional risk factors for kidney disease. In the early ART era, HIVAN comprised at least half of the cases of CKD among HIV-1 infected African American individuals. [22] In a large multicenter observational cohort study, Black race, hepatitis C co-infec-

tion, lower time-varying CD4 cell count, and higher time-varying viral load on ART were associated with higher CKD risk, and the magnitude of these risks increased with more severe CKD.[29] Hepatitis C virus, in particular, has been demonstrated as a major contributor to kidney disease in the HIV-1 infected population.[30] A large proportion of dually infected patients also use illicit drugs which may adversely affect kidney function. Cocaine, in particular, has been linked to arterionephrosclerosis, a histopathological finding linked to hypertensive kidney disease, among HIV-1 infected cocaine users despite the absence of hypertension.[31]

Among antiretroviral agents currently approved for the treatment of HIV-1, CKD has been most clearly established with nucleoside reverse transcriptase inhibitor: tenofovir particularly when used with ritonavir boosting; and protease inhibitors: indinavir, atazanavir, and to lesser extent lopinavir/ritonavir.[29,32,33] In addition, traditional risk factors for CKD such as diabetes, hypertension, and dyslipidemia are more common in HIV-1 infected individuals particularly with ART exposure.[34,35] These ART-related metabolic abnormalities likely play an important role in the development of CKD among HIV-1 infected individuals.

Similar to HIV-1 uninfected individuals with CKD, a thorough evaluation and examination of eGFR trend, urine sediment, renal sonogram, and early referral to nephrologists are important in their work-up. Given the broad spectrum of possible causes of CKD in HIV-1 infected individuals, kidney biopsy should be considered in this population particularly if the patient also has coexisting proteinuria.

Kidney toxicity of antiretroviral therapy

The course of HIV-1 infection has greatly changed with the introduction of ART not only by improving survival rates but also by reducing comorbidities directly linked to immune deficiency.[36–39] Consequently, there has been an increase of clinical interest in health conditions associated with aging in this population such as cardiovascular and bone diseases as well as potential adverse effects of long-term exposure to ART particularly those associated with nephrotoxicity. In general, the impact of ART on long-term kidney function has been beneficial with reduction in CKD risk[29], and control of HIVAN.[23] However, the potential renal adverse effects associated with prolonged exposure to certain ART are a concern. Furthermore, several antiretroviral drugs inhibit renal tubular transporters with subsequent drug-drug interactions and increases in serum creatinine concentration.

Among the currently available classes of ART drugs, established renal adverse outcomes have been linked to the use of several nucleoside reverse transcriptase inhibitors and protease inhibitors.[32] Nephrotoxicity related to the use of non-nucleoside reverse transcriptase inhibitors, entry or integrase inhibitors have been limited to case reports and a causative relationship has not been established with the use of these agents.

Tenofovir: Renal toxicity has been most clearly established with the use of tenofovir. This agent has been linked to a spectrum of renal adverse events such as acute proximal tubular injury with AKI[40], Fanconi syndrome, nephrogenic diabetes insipidus,[41] proteinuria, rapid decline in renal function (>/=3 ml/min per 1.73 m annual decline), and CKD with cumulative exposure.[42]

Fanconi's syndrome is classically characterized by proteinuria, normoglycemic glycosuria, hypokalemic renal tubular acidosis, and phosphaturia. It is important to note that patients with tenofovir-induced phosphaturia may not exhibit accompanying hypophosphatemia, and without intervention, there is a concern that phosphaturia may lead to osteomalacia and pathologic fractures.[43–45] Kidney biopsy typically reveals renal tubular injury along with proximal eosinophilic inclusions of giant mitochondria.[40]

Risk factors for tenofovir-related nephrotoxicity include older age, lower body mass, established CKD, and certain polymorphisms of the gene encoding for renal transporter involved in drug exit from proximal tubule into the urine.[46,47] Other key issues must also be considered as it may increase the risk for tenofovir nephrotoxicity. Dose adjustment of tenofovir may be overlooked in hospitalized HIV-1 infected individuals with acute illness with renal dysfunction leading to increase in drug exposure and toxicity. The use of combined one pill regimens (such as Atripla—tenofovir, emtricitabine plus efavirenz—or Quad—tenofovir, emtricitabine, plus elvitegravir/cobicistat) may limit these dose adjustments. The introduction of the new agents such as the pharmacoenhancer, cobicistat that inhibits serum creatinine secretion raising its level, adds another degree of complexity when dose adjustment is required. It is therefore crucial to monitor renal function, urinalysis, urinary protein excretion, and renal proximal tubular injury biomarkers on a regular basis in high risk patients receiving tenofovir either as a single pill and particularly when combined with other agents.

Protease Inhibitor nephrotoxicities: The use of indinavir sulfate and atazanavir sulfate has been linked to nephrolithiasis, the former to a much greater degree. Asymptomatic indinavir crystalluria is common with indinavir use occurring in two-thirds of treated patients[48,49] while the incidence of symptomatic crystalluria or nephrolithiasis has been estimated at 8 to 19% of patients on chronic therapy.[50–52] Low lean body mass was demonstrated to be the strongest risk for the development of urological symptoms in patients receiving indinavir.[50] Other risk factors include higher indinavir doses, use of ritonavir as a pharmacologic boosting agent, warm climates, and suboptimal daily fluid intake. In developed countries, indinavir has largely been replaced by next-generation PIs and is rarely used.

Prevalence of atazanavir stones is estimated to be 0.97% among those taking the drug.[53] While no associated risk factors have been found, atazanavir stones (similar to indinavir) appear to form in alkaline urine.

Nephrolithiasis should be considered in patients who develop renal colic; and may be confirmed by biochemical stone analysis. Furthermore, both indinavir sulfate and atazanavir are associated with increased incidence of CKD. Cumulative exposure to indinavir was associated with increased risk for incident chronic kidney disease, with an 11% rise in incidence per year of indinavir exposure. In this same study, atazanavir was also associated with increased risk for the development of CKD, with a 22% increase in incident CKD per year of atazanavir exposure. When atazanavir was used in combination with tenofovir, the incidence of CKD was even higher at 41% per year of exposure suggesting synergistic nephrotoxic effect.[54]

Implications of kidney disease

Similar to the general population, there is a strong evidence linking AKI, proteinuria, and CKD with adverse outcomes among HIV-1 infected individuals. The risk is more prominent in Black patients with proteinuria compared to Caucasians, suggesting that Black individuals are potentially more susceptible to vascular injury.[55] In a nested case-control study of 315 predominantly Black HIV-1 infected individuals, 63 of whom had cardiovascular events, the odds of a cardiovascular event was 1.2-fold

greater per 10-mL/min/1.73 m^2 lower eGFR and was 2-fold greater among individuals with proteinuria independent of other risk factors.[56] In a large population of HIV-1 infected women, a graded relationship between albuminuria and the risk of all-cause and AIDS mortality was identified.[57] In a large predominantly HIV-1 infected male cohort followed for a mean of 5.7 years, the incidence of all-cause mortality, ESRD, cardiovascular disease, and heart failure increased incrementally with the severity of AKI.[58]

Management of kidney disease in HIV-1 infected Individuals

Patients with eGFR <60 mL/min per 1.73 m^2 or proteinuria (≥1+) should be referred to a nephrologist with consideration for kidney biopsy. Drug dosing in HIV-1 infected individuals with kidney disease should be adjusted according to their level of kidney function[32] as incorrect drug dosing in HIV-1 infected individuals may explain the higher mortality associated with kidney disease in this population.[9,59] Based on observational studies showing the efficacy of ART in treating HIVAN[23], ART initiation is recommended in patients diagnosed with HIVAN irrespective of immune status. The findings of severe interstitial inflammation on kidney biopsy in patients with HIVAN may explain the partial efficacy of steroids in treating HIVAN.[60] Suggested dose is 1 mg/kg/day of prednisone for 4 weeks with subsequent taper. Angiotensin-converting enzyme inhibitors can be utilized as an adjunctive therapy if tolerated. The use of ART in patients who are diagnosed with HIVICK has been shown less effective.[24]

Given the strong link between both acute and chronic kidney disease with cardiovascular disease observed in HIV-1 infected individuals, treatment needs to encompass management of blood pressure, diabetes, and dyslipidemia. All modalities of renal replacement therapy should be entertained and discussed with those who progress to ESRD. No special precautions are required for HIV-1 infected individuals on maintenance dialysis and no necessity to assign a dedicated nurse or an isolated chair to those patients while on hemodialysis.

Those with undetectable viral load, CD4>200, and on stable ART should be considered for kidney transplant.[61] It is advisable to consider substituting protease inhibitors and potentially nephrotoxic antiretroviral agents prior to transplant to avoid drug-drug interactions with immunosuppressive agents as well as renal graft dysfunction respectively. ❖

Table 1: Creatinine clearance and eGFR equations

Equation	Expression
Cockcroft-Gault [62]	CrCl = ([140-age)] x weight/(72 xSCr) x 0.85 if female
Re-expressed MDRD[63]	eGFR = 175 x standardized $SCr^{-1.154}$ x $age^{-0.203}$ x 0.742 if female x 1.212 if Black
CKD-EPI[64*]	eGFR=141 x min $(SCr/\kappa,1)^{\alpha}$ x max $(SCr/\kappa,1)^{-1.209}$ x 0.933^{age} x 1.018 if female x 1.159 if Black where κ is 0.7 for males and 0.9 for females; α is -0.411 for males and -0.329 for females; min indicates minimum of SCr/κ or 1; and max indicates maximum of SCr/κ or 1

Abbreviations: CrCl, creatinine clearance; SCr, serum creatinine; MDRD, modification of diet in renal disease; CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; eGFR, estimated glomerular filtration rate

Units: age in years, weight in kg, SCr in mg/dl

* A CDD-EPI calculator is now available as a smart phone app, see the QxMD website (*http://www.qxmd.com/calculate-online/nephrology/ckd-epi-egfr*) for more information.

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POST TEST — Page 1 of 1

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1. For kidney disease screening, which of the following is considered most accurate in HIV-1 infected populations?
   - A. Serum creatinine alone
   - B. Serum creatinine based- Cockcroft-Gault formula
   - C. Serum creatinine with the serum cystatin C based equation (hybrid equation)
   - D. Serum creatinine based CKD-EPI equation

2. Which of the following is NOT true about acute kidney injury (AKI) or chronic kidney disease (CKD)?
   - A. AKI is defined as an increase in serum creatinine by ≥0.3 mg/dl (≥26.5 µmol/l) within 48 hours
   - B. AKI is defined as an increase in serum creatinine of ≥1.5 times baseline
   - C. CKD is defined as the presence for more than 3 weeks of an estimated GFR of < 60 ml/min
   - D. CKD is defined as kidney damage (presence of proteinuria or abnormalities on ultrasound) with or without decrease eGFR for more than 3 months

3. Which of the following explains the high risk for AKI in HIV-1 infected individuals?
   - A. Extra-renal pathology, such as hemodynamic renal failure due to heart failure, pancreatitis, hepatic cirrhosis or renal outflow obstruction
   - B. Specific renal parenchymal diseases, such as allergic interstitial nephritis, acute glomerular, or vasculitic disorders
   - C. Antiretroviral medications, particularly tenofovir
   - D. Non-specific disorders such as ischemic or toxic injury
   - E. All the above

4. In the study cited in this article, the majority of cases of acute allergic interstitial nephritis (AIN)—a common cause of AKI in HIV-1 infected individuals—was due to:
   - A. Non-steroidal anti-inflammatory drugs
   - B. Sulfamethoxazole/trimethoprim
   - C. Antiretroviral medications
   - D. A and B
   - E. All the above

5. Among hospitalized patients with HIV-1, what percentage develops AKI?

   A. 3% B. 6% C. 12% D. 18%

6. Which of the following is NOT a risk factor for AKI in people with HIV?
   - A. Pre-existing hypertension
   - B. Diabetes
   - C. Underlying kidney disease
   - D. Lung disease
   - E. Low CD4 cell counts and high HIV-1 RNA levels

7. Which of the following are accurate signs of untreated HIV-1 associated nephropathy (HIVAN)?
   - A. High serum creatinine levels with nephrotic range (>3 g/24h) proteinuria
   - B. Low CD4 count and/or high viral load
   - C. Renal sonogram
   - D. Hypertension
   - E. A and B

8. How is HIVAN treated?
   - A. ART
   - B. Angiotensin converting enzyme inhibitors/angiotensin receptor blockers
   - C. Glucocorticoids
   - D. B and C only
   - E. All of the above

9. Which of the following is NOT a risk factor for chronic kidney disease?
   - A. European descent
   - B. Hepatitis C co-infection
   - C. Lower time-varying CD4 cell count and higher time-varying viral load
   - D. Antiretroviral drug use, particularly tenofovir, indinavir and atazanavir
   - E. Diabetes, hypertension, and dyslipidemia

10. Renal adverse outcomes have been linked to which of the following antiretroviral agents?
    - A. Tenofovir
    - B. Indinavir sulfate
    - C. Atazanavir sulfate
    - D. B and C
    - E. All of the above

11. In reference to HIV-1 infected individuals on maintenance hemodialysis, which of the following is most accurate?
    - A. No special precautions are required
    - B. It is necessary to assign a dedicated nurse to these individuals
    - C. It is necessary to dedicate an isolated chair to these individuals
    - D. B and C

The Kidney in HIV-1

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Indicate the type of continuing education credit you wish to obtain as a result of your participation in this activity.

☐ **Nurses:** 1.06 CNE Contact Hour(s). Contact Hours Claimed: _____

☐ **Physicians:** 0.75 *AMA PRA Category 1 Credit(s)™*: Credits Claimed: _____

☐ **General:** Continuing Education Units (CEUs) (up to 0.1) Claimed: _____

One credit/contact hour for each hour of participation. Continuing Education Units: one unit per ten hours of participation.
I attest that I have completed this activity as designed. I will report the number of credits/contact hours claimed during my filing of continuing education credit with professional organizations, licensing boards, or other agencies.

Signature Date

Release date: December 1, 2013 • Expiration date: Credit for this activity will be provided through November 30, 2015.
A CE credit letter will be mailed to you in approximately 4 weeks.

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CE Activity Code: 16HH01 — This form may be photocopied.

The Kidney in HIV-1

EVALUATION FORM

CE CONTINUING EDUCATION

RUTGERS

The planning and execution of useful and educationally sound continuing education activities are guided in large part by input from participants. To assist us in evaluating the effectiveness of this activity and to make recommendations for future educational offerings, please take a few moments to complete this evaluation form. Your response will help ensure that future programs are informative and meet the educational needs of all participants.

Please note: CE credit letters and long-term credit retention information will only be issued upon receipt of completed evaluation form.

PROGRAM OBJECTIVES: Having completed this activity, are you better able to:

		Strongly Agree				Strongly Disagree
Objective 1:	List the indicators of renal injury in HIV infected patients	5	4	3	2	1
Objective 2:	Recognize the array of kidney disorders in HIV infected patients	5	4	3	2	1
Objective 3:	Describe the management of kidney disease in HIV infected individuals	5	4	3	2	1

OVERALL EVALUATION:	Strongly Agree				Strongly Disagree
The information presented increased my awareness/understanding of the subject.	5	4	3	2	1
The information presented will influence how I practice.	5	4	3	2	1
The information presented will help me improve patient care.	5	4	3	2	1
The author demonstrated current knowledge of the subject.	5	4	3	2	1
The program was educationally sound and scientifically balanced.	5	4	3	2	1
The program avoided commercial bias or influence.	5	4	3	2	1
The self-assessment was appropriate and helpful.	5	4	3	2	1
Overall, the program met my expectations.	5	4	3	2	1
I would recommend this program to my colleagues.	5	4	3	2	1

Based on the content of the activity, what will you do differently in the care of your patients? (check one)

- ☐ Implement a change in my practice.
- ☐ Seek additional information on this topic.
- ☐ Do nothing differently. Current practice reflects activity recommendations.
- ☐ Do nothing differently as the content was not convincing.
- ☐ Do nothing differently. System barriers prevent change.
- ☐ Not applicable. I do not see patients in my current position.

If you anticipate changing one or more aspects of your practice as a result of your participation in this activity, please provide us with a brief description of how you plan to do so.

_____

May we contact you in two months to see how you are progressing on the changes indicated above?

☐ Yes. Please provide your email address. _____

☐ No. I do not wish to participate participate in the follow-up assessment.

If you are not able to effectively implement what you learned at this activity, please tell us what the system barriers are (e.g., reimbursement issues, managed care rules, formulary decisions, countervailing practice guidelines, etc).

_____

Please list any topics that you would like addressed in future educational activities.

_____

CE CONTINUING EDUCATION

Injecting Drug Use Trends in New Jersey

Release Date: December 1, 2013 • Expiration Date: November 30, 2015 • Course Code: 16HH02 • Nursing credit for this activity will be provided through November 30, 2015

SPONSOR

Sponsored by François-Xavier Bagnoud Center, School of Nursing, Rutgers, The State University of New Jersey and the Center for Continuing and Outreach Education at Rutgers Biomedical and Health Sciences.

FUNDING

This activity is supported by an educational grant from the New Jersey Department of Health (NJDOH)—Division of HIV, STD and TB Services, through an MOA titled "Education and Training for Physicians and other Healthcare Professionals in the Diagnosis and Treatment of HIV/AIDS."

STATEMENT OF NEED

Current data suggest that injection drug use has shifted from the stereotypical drug users of the early HIV-era, when the face of the HIV-infected injecting drug user (IDU) was inner city, ethnic minority and low-income. Since the 1990s there has been a progressive increase in misuse and abuse of prescription pain pills, particularly in suburban and rural areas. The addiction to prescription pain pills has provided a gateway to heroin use and addiction—including heroin injection—in the same non-urban population. The skyrocketing number of suburban and rural drug overdose mortality is testament to the importance of screening all patients for addiction.

Providers need to be aware of recent shifts in risk factors for prescription pill abuse and heroin use, as they are well-placed to both prevent addiction to prescription pills and refer into care when patients show signs of addiction. The stigma surrounding drug use is also an ongoing problem, and one that makes it challenging for clinicians to have an open dialogue with patients showing signs of drug addiction. Screening approaches that are not stigmatizing and nonjudgmental are more likely to lead to successful referrals into care.

New Jersey has a number of available treatment options to which clinicians can refer patients in need of addiction or harm reduction services. The State of New Jersey keeps an up-to-date directory to support patient referral to drug treatment.

TARGET AUDIENCE

This activity is designed for physicians, nurses, social workers, health educators, and other health care professionals in New Jersey who are involved in the care of people with HIV.

METHOD OF PARTICIPATION

Participants should read the learning objectives, review the activity in its entirety, and then complete the self-assessment test, which consists of a series of multiple-choice questions. Upon completing this activity as designed and achieving a passing score of 70% or more on the self-assessment test; participants will receive a letter of credit and the test answer key four (4) weeks after receipt of the self-assessment test, registration, and evaluation materials. This activity may also be completed online at ***http://ccoe.rbhs.rutgers.edu/catalog/***.

Estimated time to complete this activity as designed is 1.04 hours for nurses, and 0.75 hour for physicians.

LEARNING OBJECTIVES

Upon completion of this activity, participants should be able to:

1. Identify the current trends in injecting drug use (IDU) in New Jersey
2. Recognize the importance of screening clients for injecting drug use and/or opiate abuse
3. Refer patients for addiction treatment

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CME

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This activity is awarded 1.04 contact hours (60 minute CH).

Nurses should only claim those contact hours actually spent participating in the activity.

CEU

Rutgers Center for Continuing and Outreach Education certifies that this continuing education offering meets the criteria for up to 0.1 Continuing Education Units (CEUs), provided the activity is completed as designed. One CEU equals 10 contact hours of participation in an organized continuing education experience under responsible sponsorship, capable direction and qualified instruction. Participants should only claim those contact hours actually spent participating in the activity.

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In order to help ensure content objectivity, independence, and fair balance, and to ensure that the content is aligned with the interest of the public, CCOE has resolved all potential and real conflicts of interest through content review by non-conflicted, qualified reviewers. This activity was peer-reviewed for relevance, accuracy of content and balance of presentation by Joanne Phillips, RN, MS and Carolyn K. Burr, EdD, RN.

Field Test: This activity was field tested for time required for participation by Bonnie R. Abedini, MSN, RN; David John Cennimo, MD; Jojy Cheriyan, MD, MPH, MPhil; Anna M. Haywood, RN, MSN; Mary C. Krug, RN, MSN, APN; Kinshasa Morton, MD; Shobha Swaminathan, MD; and Kara Winslow, BSN, RN.

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NEW JERSEY AIDSLine December 2013

Injecting Drug Use Trends in New Jersey

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Learning objectives:

By the end of this activity participants should be able to:

1. Identify the current trends in injecting drug use in New Jersey
2. Recognize the importance of screening clients for injecting drug use and/or opiate abuse
3. Refer patients for addiction treatment

Introduction

New Jersey currently ranks fourth in the nation for overall cumulative HIV cases and has the largest proportion of women infected with AIDS in the United States.[1] Of the 76,454 adults and adolescents in New Jersey reported since 1981 to have HIV or AIDS (cumulative HIV/AIDS case reports), 27,614 (36%) acquired HIV through injecting drug use, another 2,339 (3%) were men who have sex with men who were injecting drug users (IDUs), and another 3,763 (5%) acquired HIV through sex with an IDU. In total, 33,716 or 44% of New Jersey's HIV infections are attributable, directly or indirectly to injecting drug use.[2] Only Connecticut and Puerto Rico attribute a higher percentage of their HIV cases to injecting drug use.[3]

Release Date: December 1, 2013 • Expiration Date: November 30, 2015 • Course Code: 16HH02 • Nursing credit for this activity will be provided through November 30, 2015

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RUTGERS François-Xavier Bagnoud Center SCHOOL OF NURSING

Considered in isolation, the cumulative numbers of HIV transmitted through injecting drug use provide a misleading image of today's epidemic. In recent years the number and percentage of HIV cases transmitted this way have dropped dramatically in both the United States[4] and in New Jersey (see Figures 1 and 2 and Table 1):

- In 1996 1,471 New Jersey residents (including 85 men who have sex with men who are also IDUs) were reported to have acquired AIDS through injecting drug use, 41%[5] of that year's total.
- By comparison, in 2012, 56 New Jersey residents were reported to have acquired HIV or AIDS through injecting drug use, 3% of that year's total. This trend seems stable: as of the first six months of 2013, 4% of reported HIV or AIDS reports were due to injecting drug use.

The drop in HIV incidence in IDUs is mirrored by a fall in the number of reported cases of acute hepatitis C, which from 2006 to 2010 went from 90 to 28.[6] In 2011 that trend started increasing but levels are still not as high as they were in 2006.[7] There is a sizeable pool of people who are chronic hepatitis C carriers,[8] but the fact that incidence is still lower than it was six years ago, suggests that IDUs currently tend not to share injecting equipment. However, this statement is tentative and could change should there be shifts in the factors that encourage or discourage sharing of injecting equipment. Nonetheless, the increasing rate of opioid use, both legal and illicit, suggests that there is a pool of new users vulnerable to infection—similar to, but very different from, the pool of individuals at risk of HIV when that disease emerged in the IDU population in New Jersey in the 1980s.

This paper will argue that the drop in the number of IDUs diagnosed with HIV and Hepatitis C is not due to a fall in the number of people injecting drugs, as that number has actually increased. Rather, decreasing HIV prevalence rates in IDUs may be due to program efforts to increase users' access to clean syringes both through syringe access programs (SAPs) and pharmacies; efforts to promote safer injection practices; effects of antiretroviral therapies on infectivity of IDUs; and possible changes in risk networks and other social mixing patterns that vary from place to place.[4] This paper will review some of the reasons for the increase in misuse of prescription pain killers and the resulting increase in heroin use as well as suggestions to prevent and address this public health crisis.

Figure 1. Percentage of AIDS or HIV/AIDS cases in New Jersey due to injecting drug use

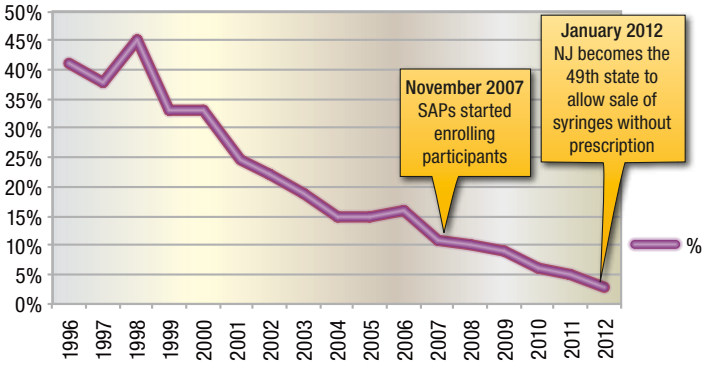


Figure 2. Number of AIDS or HIV/AIDS cases in New Jersey due to injecting drug use

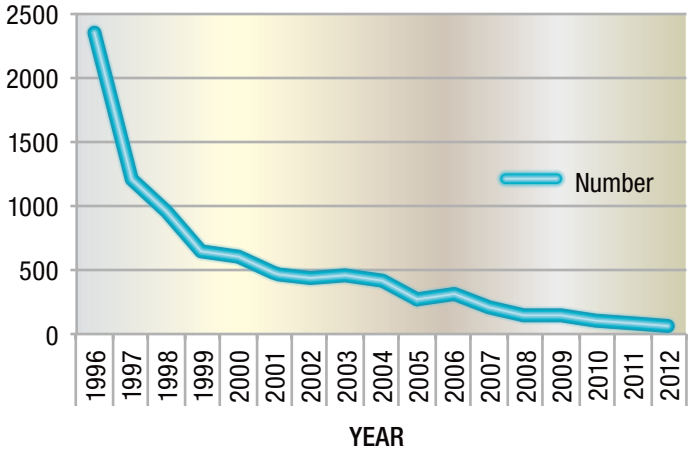


Table 1. Number (percentage) of AIDS or HIV/AIDS cases in New Jersey due to injecting drug use, by year of report

Year of report	IDU (%)	MSM/IDU (%)	Total (%*)
1996[5]**	1,386(39%)	85 (2%)	2,471 (41%)
1997[9]**	1,135 (36%)	74 (2%)	1209 (38%)
1998[10]**	878 (42%)	68 (3%)	946 (45%)
1999[11]**	628 (32%)	26 (1%)	654 (33%)
2000[12]**	569 (31%)	32 (2%)	601 (33%)
2001[13]***	548 (28%)	34 (2%)	583 (30%)
2002[14]	420 (21%)	23 (1%)	443 (22%)
2003[15]	427 (18%)	22 (1%)	449 (19%)
2004[16]	374 (14%)	34 (1%)	408 (15%)
2005[17]	257 (14%)	16 (1%)	273 (15%)
2006[18]	295 (15%)	19 (1%)	314 (16%)
2007[19]	188 (10%)	18 (1%)	206 (11%)
2008[20]	144 (8%)	11 (1%)	155 (8%)
2009[21]	128 (8%)	10 (1%)	138 (9%)
2010[22]	83 (5%)	18 (1%)	101 (6%)
2011[23]	67 (4%)	16 (1%)	83 (5%)
2012[2]	48 (3%)	8 (0%)	56 (3%)
2013 (Jan–June) [24]	34 (3%)	7 (1%)	41 (4%)

* Refers to percentage of cases reported in THAT year, percentages in this table do not add up.

** AIDS case reports, all other years are HIV and AIDS case reports

*** AIDS case reports, based on data as of September 30, 2001 for the 12-month reporting period 10/1/01-09/30/01.

Notable dates:

- Late November 2007, syringe access programs started enrolling participants.[25]
- January 2012, New Jersey becomes the 49th state to allow the sale of syringes without a prescription.

Note to reader: In 2011 it was estimated that a third (32%) of prevalent cases did not have risk information, thus, the numbers in this table are likely to be underestimates. Information available at: http://www.nj.gov/health/aids/aidsqtr.shtml

Changing face of injecting drug use

A 1993 study conducted by the New Jersey Department of Health, determined that 181 people with HIV died in Essex and Hudson counties between 1986–1987; 86 of whom were IDUs. These 86 cases were predominantly African American men in the 30–44 year age range.[26] This high death rate of African American IDUs in inner cities was the catalyst for this group to serve as the face of injecting drug use through most of the 1980s, 1990s and into the 2000s. However, this stereotype did not represent the typical IDU by the early 1990s.

A report by CDC found that by 1993, the proportion of persons admitted to New Jersey addiction treatment centers for illicit drug use who reported injecting drugs had increased, reversing a decline that began in approximately 1980.[27] This report suggested substantial increases in injection use among young adult heroin users throughout the state and an increase in heroin use among young adults who resided in suburban and rural New Jersey. This trend has continued into the 2000s and, over the past decade, become more and more noticeable. As Goldberg and Queally, Star-Ledger reporters, put it: "The face of heroin isn't thugs on street corners, peddling to junkies. It's teenagers in their bedrooms sending texts. The war against hard drug use moved from the state's urban centers to quiet suburbs years ago."[28]

Drug overdoses in New Jersey

Suburban opioid use—both injected and non-injected—in adults less than 26 years of age has become a major public health concern in New Jersey. In the first nine months of 2013, there were 89 deaths from drug overdose in Ocean County, half linked to heroin overdose.[29] Drug overdose has become the leading cause of accidental death in New Jersey. In 2009 in New Jersey, 752[30] people died from drug overdoses; in comparison 583[31] died from motor vehicle-related causes. Deaths are just the tip of the iceberg: while non-fatal overdoses have been described anecdotally, specific statistics on these events are not currently available.

Table 2. 2009 overdose deaths in New Jersey

Cause	Number of deaths
Prescription opioid overdose	180
Heroin overdose	110
Cocaine overdose	80
Combination of prescription opioids, heroin and cocaine	50
Prescription opioids and heroin	109
Prescription opioids and cocaine	55
Combination of heroin and cocaine	65
Other drugs	103
Total drug overdoses	**752**

According to the Drug Policy Alliance, almost 6,000 people have died from drug overdoses in New Jersey since 2004. Opioids were involved in more than 75% of drug overdose deaths in New Jersey in 2009. The five counties with the highest numbers of drug overdose deaths are Camden, Essex, Middlesex, Monmouth and Ocean.

Table 3. 2009 overdose deaths by county

County	Number of deaths
Atlantic	48
Bergen	32
Burlington	35
Camden	97
Cape May	15
Cumberland	13
Essex	81
Gloucester	36
Hudson	41
Hunterdon	3
Mercer	22
Middlesex	73
Monmouth	69
Morris	28
Ocean	63
Passaic	28
Salem	4
Somerset	12
Sussex	8
Union	34
Warren	10
Total	**752**

Table 4. 2009 overdose deaths by gender

Gender	Number of deaths
Women	208
Men	543
Total	**751**

Table 5. 2009 overdose deaths by race

Race/ethnic background	Number of deaths
Non Hispanic White	559
Non Hispanic Black	133
Hispanic	54
Asian or Pacific Islander	2
Total	**748**

Source Tables 2–5: Drug Policy Alliance. *New Jersey Overdose Statistics*. Available at: http://www.drugpolicy.org/sites/default/files/Overdose%20Prevention%20Campaign%20OD%20Stats%20NJ_0.pdf

continued on page next page

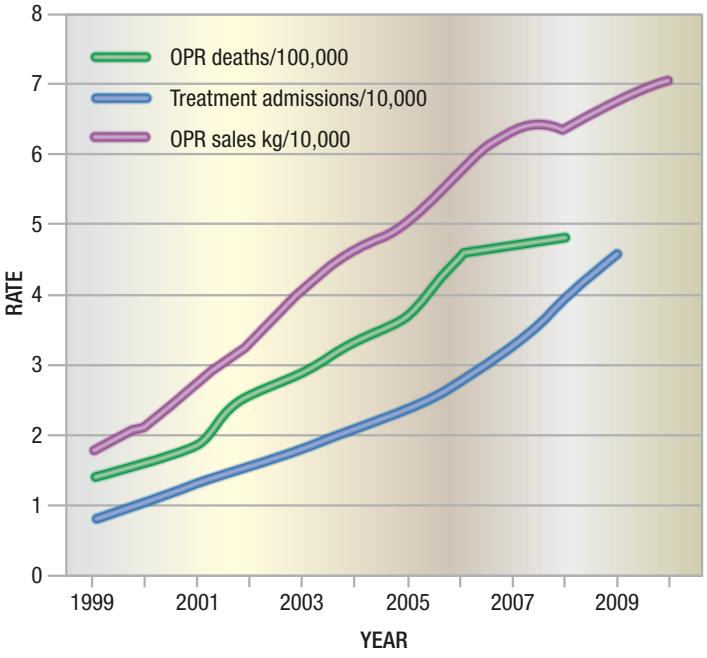
Nonmedical use of prescription painkillers: national trends

Many sources, both published and anecdotal,[32, 33] have stated that the use and misuse of prescription pills is becoming more prevalent among suburban and rural young people in the United States and leading to heroin addiction. Experts at the New Jersey State Commission of Investigators testified[33] that prescription pills are easily accessible to teenagers, and have become a "gateway drug" to heroin. An understanding of the illicit drug epidemic, however, also requires and understanding of the prescription pill epidemic.

In November 2011, the Centers for Disease Control and Prevention reported deaths from prescription painkillers had reached epidemic levels.[34] In 2010, the number of overdose deaths from prescription painkillers was greater than those from heroin and cocaine combined. According to the CDC, in 2010, about 12 million Americans (age 12 or older) reported nonmedical use of prescription painkillers in the past year. According to CDC, in 2010:

- Nearly 15,000 people died of an overdose involving prescription painkillers.
- 1 in 20 people in the US (age 12 or older) reported using prescription painkillers for nonmedical reasons.
- Enough prescription painkillers were prescribed to medicate every American adult around-the-clock for a month.

Figure 3. Rates of opioid pain reliever (OPR) overdose death, OPR treatment admissions, and kilograms of OPR sold, United States, 1999–2010



Source: CDC, *MMWR*. "Vital Signs: Overdoses of Prescription Opioid Pain Relievers — United States, 1999—2008" November 4, 2011 / 60(43);1487-1492. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm?s_cid=mm6043a4_w#fig2

In New Jersey, addiction treatment admissions for opiates other than heroin for New Jersey's youth and young adults (25 years old and younger) represented nearly half (46 percent, 3,304 admissions) of all other opiate use admissions in 2010 and increased a staggering 1,145 admissions from 2009. These admissions are for non-prescription use of methadone, codeine, morphine, oxycodone, hydromorphone, meperidine, opium, and other drugs with morphine-like effects.[35] Heroin addiction treatment admissions for this age group have also climbed to 5,815 in 2010, more than 1,100 more than in 2005. Overall heroin admissions have declined slightly from 2005 to 2010, from 23,377 to 21,942 annually. However, heroin remains the primary drug of choice at admission, representing 31.6 percent of total admissions in 2010.[33]

What happened?

Since 1999, sales of prescription painkillers in the United States have quadrupled.[36] There are many reasons for this increase, both legitimate and illegitimate.

The modern field of pain medicine is very new, having developed only in the past two to three decades. Prior to this time, treatments for pain were limited and standardized tools for pain assessment were non-existent. It is now well-recognized that historically pain was both significantly under-treated and under-recognized. On this foundation, the medical community sought to improve the care of patients by ensuring their pain was recognized and treated.[37]

One issue that both led and sustained the trend to prescribe more painkillers, and one that has received inadequate attention is the "Pain as the 5th Vital Sign" campaign that the Veterans Health Administration launched in 1999, and the Joint Commission pain awareness campaign launched in 1996. Directly from their website, for accreditation they state, "On January 1, 2001, pain management standards went into effect for Joint Commission accredited ambulatory care facilities, behavioral health care organizations, critical access hospitals, home care providers, hospitals, office-based surgery practices, and long term care providers. The pain management standards address the assessment and management of pain. The standards require organizations to: recognize the right of patients to appropriate assessment and management of pain; screen patients for pain during their initial assessment; and, when clinically required, during ongoing, periodic re-assessments educate patients suffering from pain and their families about pain management". Some question, however, whether pain management had been improved by redefining it as the 5th vital sign.[38]

A second issue that has added to the prescription drug abuse debate is the increasing emphasis on patient satisfaction, a poorly described measurement that has nonetheless become a common metric when discussing health care quality. Doctors complain that trying to improve patient satisfaction often results in pressure to do things that may not be in the best interest of health care. This was underscored by a study that showed improved patient satisfaction correlated with increased mortality.[39] The current consumer model of health care combined with the above factors has certainly contributed to the increased use of pain medications that are addictive and contribute to the problem.

Injecting Drug Use Trends in New Jersey

Some reports blame the black market supply of prescription painkillers on unscrupulous, yet qualified physicians who practice "improper prescribing of pain medication". Florida, in particular has become the haven of black marketeers because of its inadequate tracking and monitoring of prescription pain relieving medications.[40] But it happens in New Jersey as well. According to a report from the State of New Jersey Commission on Investigation "Some medical management companies with names that incorporate benign terms like "pain management" and "wellness" have transformed street-corner drug-dealing into an orderly and seemingly ordinary business endeavor, except for the hidden financial backing from individuals linked to organized crime, the multiple bank accounts for money-laundering, the expert help of corrupt physicians and the shady characters who recruit and deliver customers and provide security."[41]

Regardless of the source of pills on the street, the transition from pills to heroin "happens when the medicine cabinet runs dry and they can no longer afford, on the black market, to use the pill form and transition on to cheap bags of heroin," said John Hulick, head of Governor Chris Christie's Council on Alcohol and Drug Abuse(GCADA). Goldberg and Queally summarized the supply and subsequent transition from pills to heroin quite eloquently: "The [heroin] market was flooded, the price has dropped, and with a generation of young, tech-savvy opiate addicts running low on cash and [prescription] pills, the demand [for heroin] has exploded. … There were so many painkillers out there in people's medicine cabinet that it just created a massive wave of heroin users. When the pills became too scarce or too expensive, addicts still needed to get high and so they switched to heroin." Rick Incremona, first assistant prosecutor in Monmouth County, likened it to switching from a name brand to the generic. "They like the high they have gotten from prescription narcotics but are looking for a cheaper, more readily available alternative," and they found it in heroin.

Heroin in New Jersey is roughly 50% pure, some of the highest quality in the nation, according to Special Agent Douglas Collier, spokesman for the state office of the U.S. Drug Enforcement Administration (DEA).[28] Other reports suggest that the purity is greater than 60%[27]—remarkable when compared to the quality of heroin on the streets 40 years ago, which was less than 10%.[27] Colombian drug smugglers move high-grade heroin directly into the area through Newark Liberty International Airport and ports in Newark, Elizabeth and Camden. The easy access shortens the journey from poppy fields in South America to drug addicts in New Jersey's cities and suburbs, which "ups the purity and lowers the price."[28] Heroin of this quality is highly addictive and withdrawal very difficult. In many of the cases of heroin-addicted patients, their pattern began with inhalation with subsequent transition to injection drug use as tolerance rose.

The trend described by many newspapers and GCADA has been witnessed by staff at Project Access at the North Jersey Community Research Initiative (NJCRI) in Newark. NJCRI staff have seen an increasing number of suburban youth seeking syringes at their SAP. Bob Baxter, NJCRI's Harm Reduction Program Coordinator, stated in a recent interview that at least 60% of the new cases of heroin users participating in the SAP are young, white, suburbanites. Baxter also reported that there were few new African American or Hispanic IDU clients seeking services, a finding supported by a CDC study.[27] CDC credits the decrease in ***urban*** (not suburban or rural) heroin use to intensive HIV prevention outreach and education activities in these communities.

In 2006, the state of New Jersey—by passing Public law 2006, c. 99, the Blood-borne Disease Harm Reduction Act—created up to six demonstration Syringe Access Programs (SAPs) across the state. Between November 2007 and July 2009, five SAPs were established in areas with a high prevalence of HIV attributable to IDU. The SAPs provide patients with clean needles and syringes, in exchange for used needles, and provide access to a range of health care services. The SAPs in New Jersey are listed at the end of this article.

continued on page next page

Screening, harm reduction and prevention

The State of New Jersey Commission of Investigation report[41] offered 10 recommendations for statutory and regulatory reform, including the enhancement of the New Jersey Prescription Monitoring Program (NJPMP). The NJPMP was passed by the New Jersey legislature in 2007, and went into effect in 2012 with the purpose of halting the abuse and diversion of prescription drugs. The NJPMP is a statewide database for prescribers and pharmacists to track the quantity of opiates given to patients. The NJPMP enables prescribers and pharmacists who have registered with the program to request the prescription history of the patient relative to controlled dangerous substances and human growth hormone. If a patient is identified as having a possible issue regarding drug use, the prescriber can refer that patient for treatment.[42] For more information about NJPMP as well as other policy initiates led by the State of New Jersey, see cover article.

Despite this monitoring of opiate prescriptions, treatment for prescription drug addiction is limited. One author noted "Of those in need of addiction treatment, only 11% receive it… less than 6% of referrals to treatment come from healthcare providers". Many believe that these numbers show a failure to identify risky behavior.[43] Given recent trends in prescription painkiller use, the public looks to prescribing clinicians to be judicious in their prescribing practice and to screen for addiction.

There is a great deal of controversy over the use of the term "addiction" in medicine. For many years, terms like "dependence" and "abuse" were favored because they were easier to categorize. The classification of patients using the Diagnostic and Statistics Manual of Mental Disorders (DSM) depends on patients fitting into a category where they either have something or they don't. Addiction develops with a process, and the precise moment when someone moves from using a drug or alcohol to being addicted is hard to define. In chronic pain, matters are made worse because although the drugs are prescribed, patients may develop behaviors of excessive use, doctor shopping, and diversion that disorder their lives. Some experts feel that these behaviors only develop when patients are receiving inadequate pain control and use the term "pseudo-addiction" for behaviors usually associated with addiction in these patients, but other authors contend that disordering behavior related to opiates is addiction.

At their Pain Treatment Program at Johns Hopkins Hospital Dr. Glenn Treisman and Dr. Michael Clark have found the following definition of addiction useful: ***"the increasing use of a drug or medication despite increasing consequences that disrupt function in several areas of life"***.[44] Effective treatment of chronic pain should lead to increased function and capacity and should help patients overcome deficits produced by their pain; the increasing use of opiates despite increasing dysfunction fits this definition and has been useful in helping patients to engage in rehabilitation and detoxification. Because of the risk of addiction, clinicians should monitor the patient's level of function over time, including, if possible, the use of outside informants. The warning signs of impending addiction include:

- Changes in characteristic behaviors, such as hygiene, keeping appointments, running out early, deception
- Problems with occupations or relationships
- Evidence of undisclosed medication use, such as Emergency Department visits

Treisman and Clark have also described the conditioning effects of opiate drugs on behavior on patients with chronic pain, that is, these drugs will increase behaviors that occur in proximity to their administration and ultimately in proximity to their being provided. In other words, patients addicted to opiate medications will return to places they have used opiates, often have "triggered" cravings for opiates in locations or circumstances that are associated with previous opiate use, and can even develop conditioned withdrawal symptoms, in which the physiological symptoms of opiate withdrawal (nausea, gastrointestinal cramping, "flu-like" runny noses and malaise, and diarrhea and vomiting) can be triggered by environmental cues and stimuli.[44]

If a provider suspects that a new patient has an opiate addiction, further data collection via interview and use of reliable and valid screening instruments is warranted. The Substance Abuse and Mental Health Services Administration (SAMHSA) has a number of screening tools available for clinicians to assess for opiate addiction. The Addiction Severity Index (ASI), and the ASI Lite, a shortened version of the ASI, are both recommended.[45]

Stigma and treatment

Once a clinician is aware that a substance abuse problem exists, referral for treatment is the next step. Sometimes, however, the stigma surrounding drug use limits the provision of effective care. A study published in 2007[46] examined the impact of stigma on 197 patients in substance abuse treatment from 15 residential and outpatient substance abuse treatment facilities.

Study participants reported experiencing fairly high levels of enacted, perceived, and self-stigma. Data supported the suggestion that the current treatment system may actually stigmatize people in recovery in that people with more prior episodes of treatment reported a greater frequency of stigma-related rejection. IDUs, compared to non-IV users, reported more perceived stigma as well as more often using secrecy as a method of coping. The study supported the idea that there are three conceptually and empirically distinct measures of stigma:

- **Enacted stigma** refers to directly experienced social discrimination such as difficulty in obtaining employment, reduced access to housing, poor support for treatment, or interpersonal rejection. The most commonly reported experience (60%) was believing they were treated unfairly because they were known to have abused substances; 46% felt that others were afraid of them once their substance abuse became known and 45% felt some of their family gave up on them after they found out about their substance use. The group also reported rejection from friends and discrimination at work.
- **Perceived stigma** refers to beliefs that members of a stigmatized group have about the prevalence of stigmatizing attitudes and actions in society. Participants believed that most people with substance abuse problems are devalued or discriminated against. Perceived stigma can also deter initiation of substance abuse or experimentation with a particular mode of administration, such as injecting. As an example, some experts have suggested that the increase of injecting drug use might, in part, be due to the breakdown of perceived stigma towards this method of drug administration. The stigma that used to be attached to injection use particularly by white, suburban youth has greatly decreased, making it more socially acceptable with suburban youth.[47]

- **Self-stigma**, similar to internalized shame, refers to negative thoughts and feelings that emerge from identification with a stigmatized group and their resulting behavioral impact (e.g., avoidance of treatment, failure to seek employment, avoidance of intimate contact with others, diminished self-esteem/self-efficacy and lower quality of life). This study found that internalized shame was more highly related to measures of psychological functioning and quality of life than experienced rejection and perceived stigma. This result suggests that self-stigma might be a more appropriate target for stigma-related interventions in a substance abusing sample than perceived stigma or teaching them how to avoid rejection.

The study called for "addictions treatment centers to attend to the impact of stigma on their clients". The authors concluded that "there may also be room for intervention with service providers, who unfortunately are not immune to stigmatizing their own clients." It might be sensible to suggest that drug-related stigma be addressed similarly to the stigma attached to other clients (e.g., clients seeking treatment for a sexually transmitted infection or HIV testing, minors requesting family planning services): through policy reform and training.

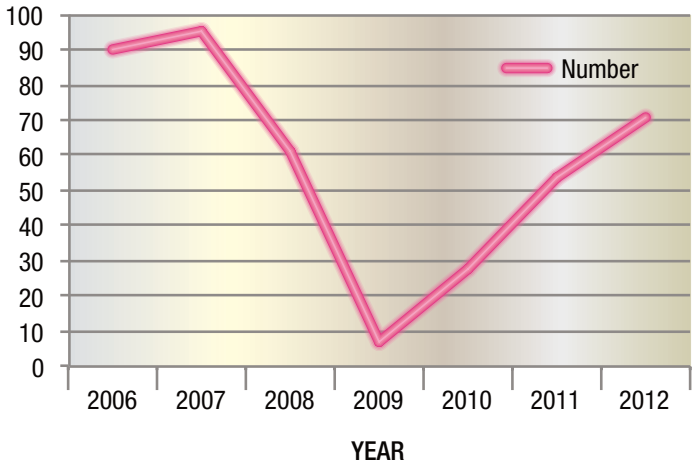
Risk of blood-borne pathogen infection

Dr. Ronald Valdiserri, Deputy Assistant Secretary for Health, Infectious Diseases, and Director, Office of HIV/AIDS and Infectious Disease Policy, U.S. Department of Health and Human Services wrote[48] of an emerging epidemic of hepatitis C infection among young IDUs in rural and suburban settings. Evidence of an emerging epidemic came from surveillance data shared by Massachusetts in 2010 that showed an increase of hepatitis C among persons aged 15–24 between 2002 and 2009. The young people being reported were from all over the state, almost all outside of metropolitan Boston, primarily White, and equally male and female. In-depth interviews with a number of these hepatitis C positive young people uncovered that most were IDUs who had started opioid use by first misusing oral oxycodone around 1–1.5 years before transitioning to injecting heroin.[49]

The editorial note that followed the Massachusetts study stated: "Although similar increases in human immunodeficiency virus (HIV) infection were not identified for this age group, increases in reports of hepatitis C infection among injection drug users might be a harbinger of increases in IDU-associated HIV."[49]

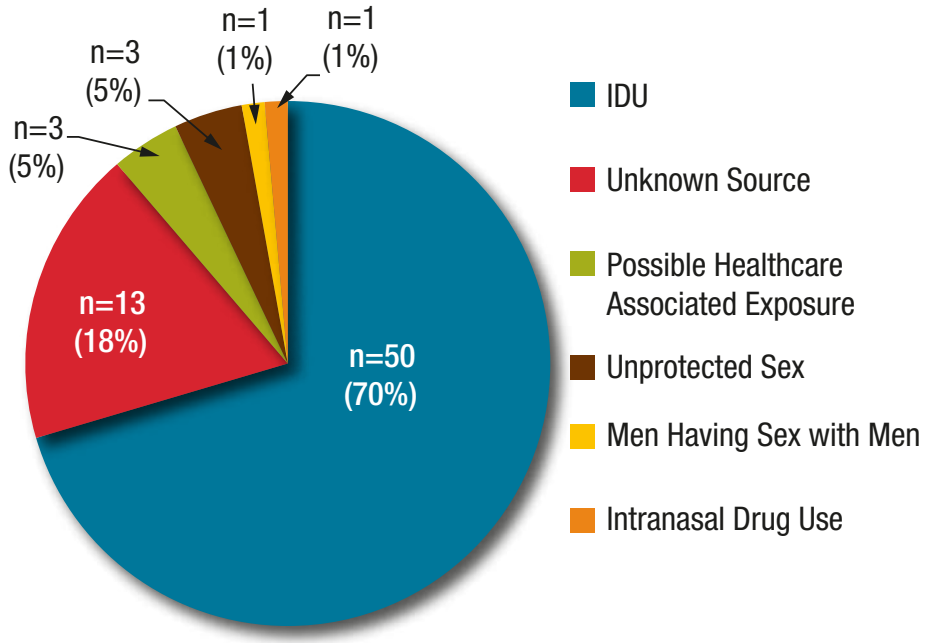
Unlike Massachusetts, New Jersey has not yet witnessed the acute hepatitis C epidemic[6,7] seen in some other states. Even though acute hepatitis C case reports went up in 2011 and 2012, the overall trend since 2006 has been downward (see Figure 4). Although acute hepatitis C reports are still relatively low (71 in 2012), it is important to note that 70% of New Jersey's cases in 2012 were attributed to injecting drug use (see Figure 5). This emphasizes the warning that an increase in the rate of injecting drug use could be a harbinger of another HIV epidemic in this population.

Figure 4. Acute hepatitis C case reports, New Jersey 2006–2012



Source: CDC. Table 4.1. Reported cases of acute hepatitis C, by state–United States, 2006–2010. *Viral Hepatitis Surveillance, United States, 2010.* And unpublished slide set from Ellen Rudowski RN, MSN, HCV Surveillance Coordinator: NJDOH, CDS. *New Jersey Hepatitis C Surveillance.* June 2013.

Figure 5. Acute hepatitis C exposure risk factors, New Jersey 2011



Source: Unpublished slide set from Ellen Rudowski RN, MSN, HCV Surveillance Coordinator: NJDOH, CDS. *New Jersey Hepatitis C Surveillance.* November 2013.

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Treatment and referrals for care

Referral for care is a problem for medical providers. Patients often do not follow referral suggestions, and they often encounter frustration in their efforts to get treatment. The available programs change and the insurance issues of obtaining care are also constantly changing.[50] Despite this, lists of programs are maintained by many substance use professionals, and a call to the emergency department social worker or similar professional may yield an list of up-to-date resources. There is clear evidence that the inclusion of on-site integrated addictions care in clinics provides better engagement and better outcomes.[50] Additionally, the presence of HIV care provision on site in substance abuse clinics has been effective in improving outcomes. Models of opiate maintenance programs that are integrated into HIV care have provided some of the best data for outcomes, and clearly improve retention, HIV treatment success and addiction treatment success.[51]

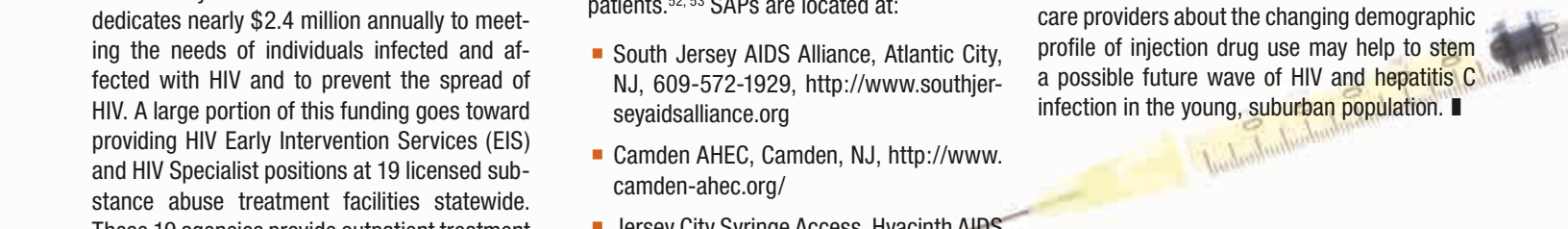
New Jersey's Division of Addiction Services dedicates nearly $2.4 million annually to meeting the needs of individuals infected and affected with HIV and to prevent the spread of HIV. A large portion of this funding goes toward providing HIV Early Intervention Services (EIS) and HIV Specialist positions at 19 licensed substance abuse treatment facilities statewide. These 19 agencies provide outpatient treatment including pre- and post-test HIV counseling.[1] A variety of resources are available for those who are using illegal drugs or misusing prescription medications. These resources include:

- **NJ Addictions Hotline:** dial 211 or 1-800-238-2333. This hotline is staffed by trained clinically supervised telephone specialists who are available 24 hours a day, 7 days a week to educate, assist, interview and/or refer individuals and families battling addictions. Calls are free and information shared is confidential. http://www.nj.gov/humanservices/das/treatment/hotlines/
- **Substance abuse treatment directory:** The State of New Jersey's Department of Human Services, Division of Addiction Services, maintains a substance abuse treatment directory at: https://njsams.rutgers.edu/dastxdirectory/txdirmain.htm; the directory includes methadone maintenance programs, a harm reduction option appropriate for some clients.
- **Syringe Access Program,** where clients can obtain clean injection equipment and referrals to care. The Access to Reproductive Care and HIV (ARCH) Nursing Program is co-located with all of the SAPs, supporting the provision of services required by the 2006 legislation. The ARCH nurses provide harm reduction counseling, referral for care—include prenatal care if the client is pregnant; HIV, TB, hepatitis and STI testing as well as immunizations. ARCH nurses have proven to be important assets to the healthcare network of New Jersey; their use of motivational interviewing and a nonjudgmental approach assists in retention and tracking of patients.[52, 53] SAPs are located at:
  - South Jersey AIDS Alliance, Atlantic City, NJ, 609-572-1929, http://www.southjerseyaidsalliance.org
  - Camden AHEC, Camden, NJ, http://www.camden-ahec.org/
  - Jersey City Syringe Access, Hyacinth AIDS Foundation, Jersey City, NJ, 201-432-1134, http://www.hyacinth.org
  - NJCRI, Newark, NJ, 973-483-3444, http://www.njcri.org
  - Point of Hope Syringe Access Program, Well of Hope Community Development Corporation, 207 Broadway, Paterson, NJ, 973-523-0700, http://www.wohcdc.org/

Conclusions

Until recently, New Jersey's HIV epidemic has been driven by injecting drug use. Although rates of injection drug use have dropped or remained level in New Jersey's urban areas, rates of injecting drug use in suburban and rural areas have increased, and been increasing since the early 1990s. This increase has been attributed to the transition in this population from an addiction to prescription opiates to heroin—which is more readily available and cheaper. The increasing price of prescription pills push young users to cheaper, more effective ways of getting high—street heroin. Concurrently, the purity, low cost, and accessibility of heroin greatly influence the numbers of drug overdoses managed in emergency departments.

Healthcare providers see many of these young people in the course of their practice, and as such are in an advantageous position to screen and provide referrals for care. Nonjudgmental, motivational interviewing remains an important tool to increase rates of referral to treatment programs. Increased awareness among healthcare providers about the changing demographic profile of injection drug use may help to stem a possible future wave of HIV and hepatitis C infection in the young, suburban population. ■



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Injecting Drug Use Trends in New Jersey

POST TEST — Page 1 of 1

CE CONTINUING EDUCATION

Questions refer to article content. To receive CME/CNE/CEU credit, complete the post test, registration and evaluation forms on-line at *http://ccoe.rbhs.rutgers.edu/catalog/* or fill in the forms below and on the following pages and mail or fax to CCOE at the address on the registration form.

1. Approximately what percent of New Jersey's ***cumulative*** HIV infections are attributable, directly or indirectly to injecting drug use?
   - A. 44%
   - B. 36%
   - C. 25%
   - D. 19%
   - E. 12%

2. Approximately what percent of New Jersey's HIV/AIDS reports in ***2012*** were attributable directly or indirectly to injecting drug use?
   - A. 36%
   - B. 25%
   - C. 19%
   - D. 12%
   - E. 3%

3. True or False: Between 2006 and 2010 the rate of acute hepatitis C in New Jersey increased from 28/100,000 to 90/100,000 population.
   - A. True
   - B. False

4. True or False: Drug overdoses and motor vehicle-related accidents cause about (within 5%) the same number of deaths per year in New Jersey.
   - A. True
   - B. False

5. The following theories were proposed in the article to explain why sales of prescription painkillers in the United States have quadrupled since 1999:
   - A. "Pain as the 5th Vital Sign" campaign launched in the late 1990s
   - B. Increasing emphasis on patient satisfaction
   - C. Improper or illegal prescribing of painkillers
   - D. A and B
   - E. All the above

6. Which best describes the NJPMP?
   - A. The NJPMP provides consumers with a way to dispose of unused medications, and to keep medications safe within their homes.
   - B. The NJPMP raises awareness about the adverse consequences of prescription drugs and includes an annual event that provides a safe, convenient, and responsible means of disposing of prescription drugs.
   - C. The NJPMP is a statewide database for prescribers and pharmacists to track the quantity of opiates given to patients.
   - D. The NJPMP allows people to call 911 when a friend or neighbor is overdosing and they will not be liable for drug use or possession charges for calling the police.
   - E. The NJPMP is the name of the Medicaid expansion that will provide expanded access to substance abuse treatment and services.

7. True or False: Treisman and Clark define addiction as "the increasing use of a drug or medication despite increasing consequences that disrupt function in several areas of life".
   - A. True
   - B. False

8. Warning signs of impending addiction include:
   - A. Changes in characteristic behaviors, such as hygiene, keeping appointments, running out early, deception
   - B. Problems with occupations or relationships
   - C. End evidence of undisclosed medication use or Emergency Department visits
   - D. All the above

9. Based on the description in this article, which of the three measures of stigma might be more appropriate to target for stigma-related interventions in a treatment program?
   - A. Enacted stigma
   - B. Perceived stigma
   - C. Self-stigma
   - D. A and B

10. Which of the following is true for New Jersey?
    - A. The increase in prevalence of injecting drug use has ***already*** witnessed emerging epidemics of hepatitis C and HIV
    - B. The increase in prevalence of injecting drug use has witnessed an emerging epidemic of hepatitis C virus infection, but ***only*** in rural and suburban settings
    - C. The increase in prevalence of injecting drug use has not yet correlated with an increase in incidence of acute hepatitis C in IDUs.
    - D. The increase in prevalence of injecting drug use has ***not yet*** correlated with an increase in incidence of HIV infection in IDUs.
    - E. C and D

CE CONTINUING EDUCATION

Injecting Drug Use Trends in New Jersey

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RUTGERS

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(1) Read the learning objectives, review the activity, and complete the post-test.

(2) Complete this registration form and the activity evaluation form on the next page. Record your test answers below.

(3) Send the registration and evaluation forms to: Rutgers Center for Continuing & Outreach Education • VIA MAIL: PO Box 1709, Newark, NJ 07101-1709 • VIA FAX: (973) 972-7128

(4) Retain a copy of your test answers. Your answer sheet will be graded and if you achieve a passing score of 70% or more, a credit letter and the test answer key will be mailed to you within four (4) weeks. Individuals who fail to attain a passing score will be notified and offered the opportunity to complete the activity again.

Online option: This activity will be posted at *http://ccoe.rbhs.rutgers.edu/catalog/* where you may obtain a credit letter upon successful completion of the online post-test and evaluation. ***Please note: CE credit letters and long-term credit retention information will only be issued upon receipt of completed evaluation form.***

SELF-ASSESSMENT TEST *Circle the best answer for each question.*	**1.** A B C D E	**2.** A B C D E	**3.** A B	**4.** A B	**5.** A B C D E	**6.** A B C D E
	7. A B	**8.** A B C D	**9.** A B C D	**10.** A B C D E		

– PLEASE PRINT –

First Name M.I. Last Name Degree

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Company/Affiliation

Preferred Mailing Address: ☐ Home ☐ Business

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Indicate the type of continuing education credit you wish to obtain as a result of your participation in this activity.

☐ **Nurses:** 1.04 CNE Contact Hour(s). Contact Hours Claimed: _____

☐ **Physicians:** 0.75 *AMA PRA Category 1 Credit(s)™*: Credits Claimed: _____

☐ **General:** Continuing Education Units (CEUs) (up to 0.1) Claimed: _____

One credit/contact hour for each hour of participation. Continuing Education Units: one unit per ten hours of participation.
I attest that I have completed this activity as designed. I will report the number of credits/contact hours claimed during my filing of continuing education credit with professional organizations, licensing boards, or other agencies.

Signature Date

Release date: December 1, 2013 • Expiration date: Credit for this activity will be provided through November 30, 2015.
A CE credit letter will be mailed to you in approximately 4 weeks.

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CE Activity Code: 16HH02 — This form may be photocopied.

Injecting Drug Use Trends in New Jersey

EVALUATION FORM

CE CONTINUING EDUCATION

RUTGERS

The planning and execution of useful and educationally sound continuing education activities are guided in large part by input from participants. To assist us in evaluating the effectiveness of this activity and to make recommendations for future educational offerings, please take a few moments to complete this evaluation form. Your response will help ensure that future programs are informative and meet the educational needs of all participants.

Please note: CE credit letters and long-term credit retention information will only be issued upon receipt of completed evaluation form.

PROGRAM OBJECTIVES: Having completed this activity, are you better able to:	Strongly Agree				Strongly Disagree
Objective 1: Identify the current trends in injecting drug use in New Jersey	5	4	3	2	1
Objective 2: Recognize the importance of screening clients for injecting drug use and/or opiate abuse	5	4	3	2	1
Objective 3: Refer patients for addiction treatment	5	4	3	2	1

OVERALL EVALUATION:	Strongly Agree				Strongly Disagree
The information presented increased my awareness/understanding of the subject.	5	4	3	2	1
The information presented will influence how I practice.	5	4	3	2	1
The information presented will help me improve patient care.	5	4	3	2	1
The author demonstrated current knowledge of the subject.	5	4	3	2	1
The program was educationally sound and scientifically balanced.	5	4	3	2	1
The program avoided commercial bias or influence.	5	4	3	2	1
The self-assessment was appropriate and helpful.	5	4	3	2	1
Overall, the program met my expectations.	5	4	3	2	1
I would recommend this program to my colleagues.	5	4	3	2	1

Based on the content of the activity, what will you do differently in the care of your patients? (check one)

- ☐ Implement a change in my practice.
- ☐ Seek additional information on this topic.
- ☐ Do nothing differently. Current practice reflects activity recommendations.
- ☐ Do nothing differently as the content was not convincing.
- ☐ Do nothing differently. System barriers prevent change.
- ☐ Not applicable. I do not see patients in my current position.

If you anticipate changing one or more aspects of your practice as a result of your participation in this activity, please provide us with a brief description of how you plan to do so.

_____

May we contact you in two months to see how you are progressing on the changes indicated above?

☐ Yes. Please provide your email address. _____

☐ No. I do not wish to participate participate in the follow-up assessment.

If you are not able to effectively implement what you learned at this activity, please tell us what the system barriers are (e.g., reimbursement issues, managed care rules, formulary decisions, countervailing practice guidelines, etc).

_____

Please list any topics that you would like addressed in future educational activities.

_____

Updated Recommendations for Tuberculosis Testing

Francesca Esposito-Weir, MPH,
Public Health Representative II-CD, NJDOH TB Program

Tuberculosis (TB) infection occurs when a susceptible person inhales droplet nuclei containing *Mycobacterium tuberculosis* complex (MTBC) organisms, typically put into the air when a person with active TB disease of the lungs, airway, or larynx coughs, sneezes, speaks or sings. The organism can linger in the air for several hours in a vaporized state, depending on environmental conditions. Once inhaled, the immune response usually limits multiplication of tubercle bacilli within 2 to 12 weeks after infection. However, viable bacilli persist in the body for years, a condition referred to as latent TB infection (LTBI). Individuals with LTBI are asymptomatic and not infectious. Those unable to fight initial infection, or experiencing a reactivation of LTBI, develop TB disease (clinically active disease, often with positive cultures). Symptoms of TB disease include weakness, fatigue, weight loss, no appetite, chills, fever, night sweats, hemoptysis and cough.

Conventional tests for laboratory confirmation of TB include:[1]

- Acid-fast bacilli (AFB) smear microscopy, which can produce results in 24 hours, and
- Culture, which requires 2–6 weeks to produce results.

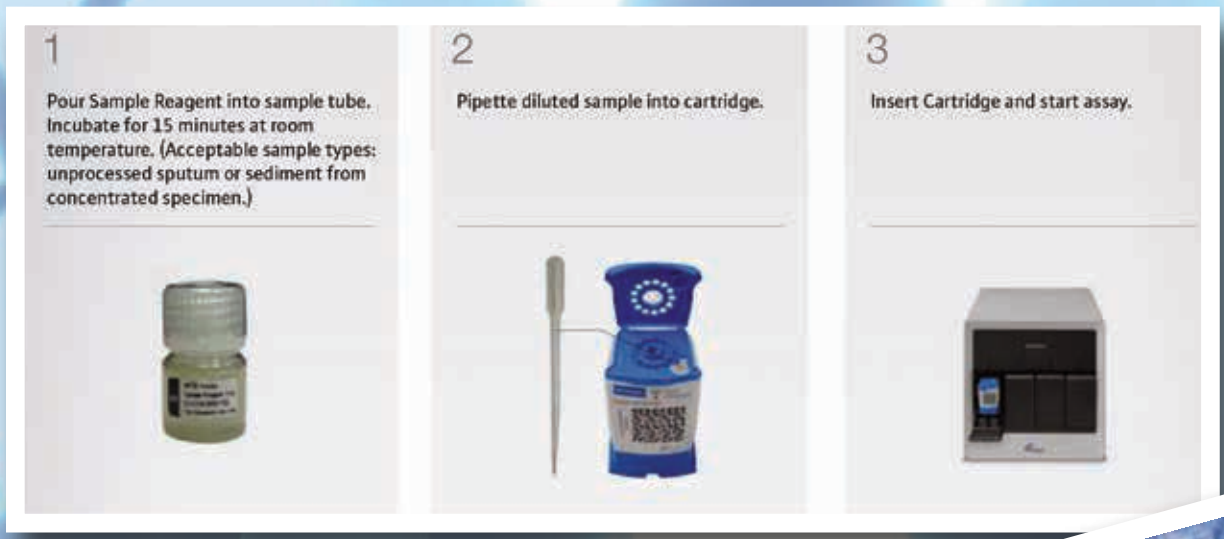
Although rapid and inexpensive, AFB smear microscopy is limited by its poor sensitivity (45%–80% with culture-confirmed pulmonary TB cases) and its poor positive predictive value (50%–80%) for TB in settings in which nontuberculous mycobacteria are commonly isolated.

In 2008, the Association of Public Health Laboratories and CDC recommended nucleic acid amplification-based (NAA) testing as standard practice in the United States to aid in the initial diagnosis of patients with suspected TB. "NAA testing should be performed on a respiratory specimen from each patient with signs and symptoms of active pulmonary TB disease for whom a diagnosis of TB is being considered (i.e., TB suspect), but has not been established." [2] New Jersey Department of Health, Tuberculosis Program also strongly recommended that hospitals consider routine utilization of NAA testing in patients suspected of having pulmonary TB with AFB positive smears and admitted to respiratory isolation.[3]

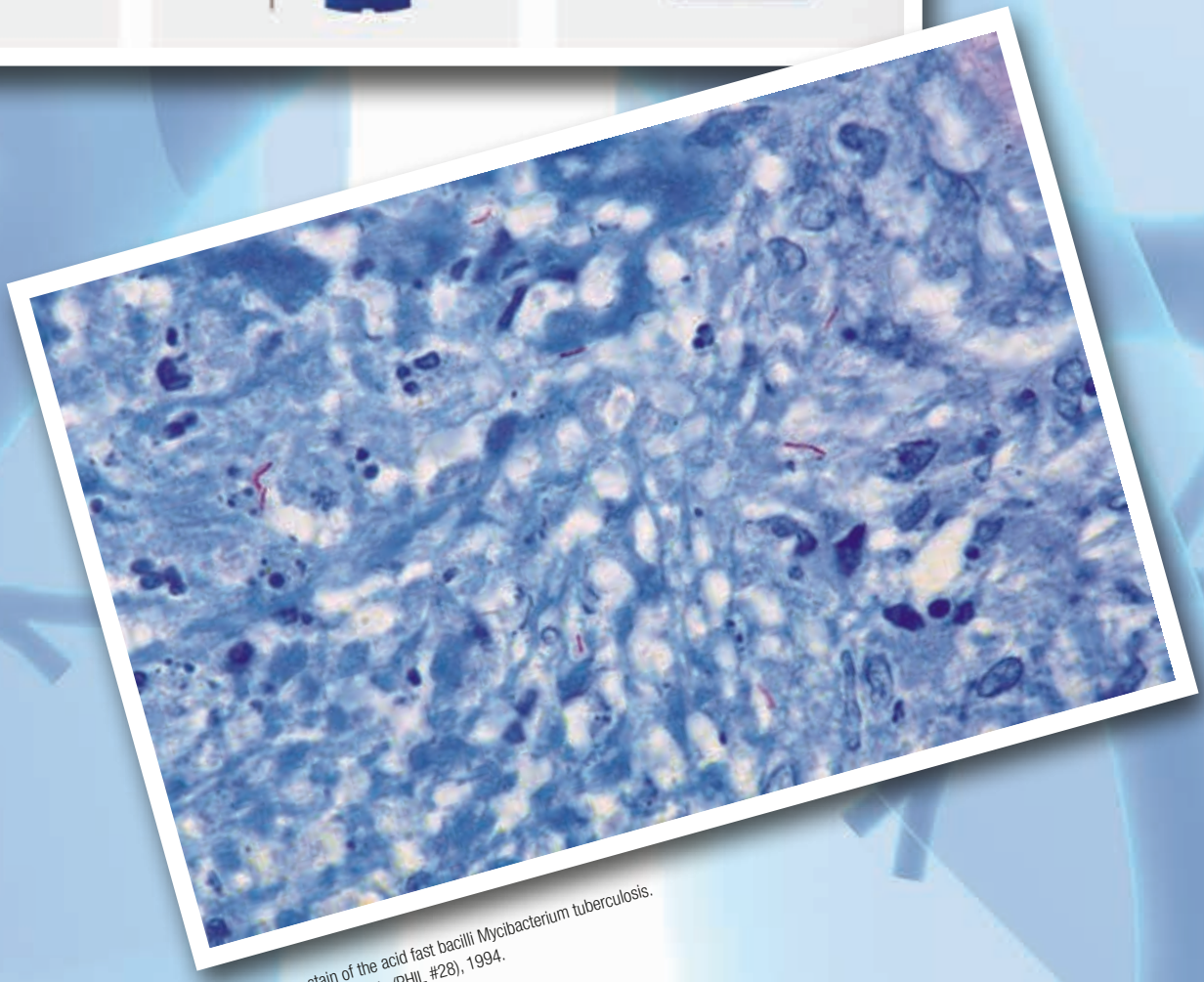
NAA tests, which provide results within 24–48 hours, have the following advantages:[1]

- Greater positive predictive value (>95%) with AFB smear-positive specimens in settings in which nontuberculous mycobacteria are common
- Ability to confirm rapidly the presence of MTBC in 50%–80% of AFB smear-negative, culture-positive specimens
- Can detect the presence of MTBC in a specimen weeks earlier than culture for 80%–90% of patients who are ultimately confirmed positive by culture

NAA testing does not replace the need for culture. All patients suspected of TB should have specimens collected for mycobacterial culture (see testing algorithm).



The three steps to use the Xpert® MTB/RIF. Total hands on-time: 2 minutes. Results available within 2 hours. Photo courtesy of Cepheid®



Ziehl–Neelsen stain of the acid fast bacilli Mycibacterium tuberculosis. CDC/Dr. Edwin P. Ewing, Jr. (PHIL #28), 1994.

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Scanning electron micrograph of *Mycobacterium tuberculosis*. Photo credit: NIAID

CDC testing and interpretation algorithm for TB diagnosis

In early 2009, CDC published revised NAA guidelines, including the following testing and interpretation algorithm for initial diagnosis.[4]

1. Routinely collect respiratory specimens (e.g., sputum), process, and test by **AFB smear** microscopy and culture. Do not delay specimen collection and testing for NAA test results.
2. Use an **NAA test** for TB to test at least one specimen per patient, preferably the first diagnostic specimen.
3. Interpret NAA test results in correlation with the AFB smear results.
   a. **NAA positive; AFB positive:** presume the patient has TB and begin anti-TB treatment while awaiting culture results. The positive predictive value of FDA-approved NAA tests for TB is >95% in AFB smear-positive cases.
   b. **NAA positive; AFB negative:** use clinical judgment whether to begin anti-TB treatment while awaiting culture results and determine if additional diagnostic testing is needed. Consider repeat NAA testing on another specimen: a patient can be presumed to have TB, pending culture results, if two or more specimens are NAA positive.
   c. **NAA negative; AFB positive:** conduct a test for inhibitors and repeat NAA test on another specimen. 3–7% of sputum specimens contain inhibitors that prevent or reduce amplification and cause false-negative NAA results.
      - If inhibitors are detected: NAA test is of no diagnostic help; use clinical judgment.
      - If inhibitors are not detected: use clinical judgment. A patient can be presumed to have an infection with nontuberculous mycobacteria if a second specimen is smear positive and NAA negative.
   d. **NAA negative; AFB negative:** use clinical judgment whether to begin anti-TB treatment while awaiting culture results. NAA tests are not sufficiently sensitive to exclude the diagnosis of TB in AFB smear-negative patients suspected to have TB.[1]

If the clinician is inexperienced with the diagnosis and treatment of TB, consultation with a TB expert should be obtained with respect to the interpretation of NAA test results in the context of other diagnostic evidence.

NAA tests identify the presence of genetic information unique to MTBC directly from respiratory samples. The NAA test uses chemical, rather than biological amplification, to produce sufficient nucleic acid so that, within a few hours, these tests can distinguish between MTBC and a nontuberculous mycobacteria in an AFB positive specimen.

Earlier laboratory confirmation of TB has enabled earlier treatment initiation and better patient care and outcomes. NAA testing can also help avoid unnecessary respiratory isolation (particularly for patients whose AFB smear-positive specimens do not contain MTBC), treatment, and contact investigation of patients without TB and can contribute to system cost savings in patients with HIV infection, homelessness, or substance abuse, compared with smear microscopy alone.[4]

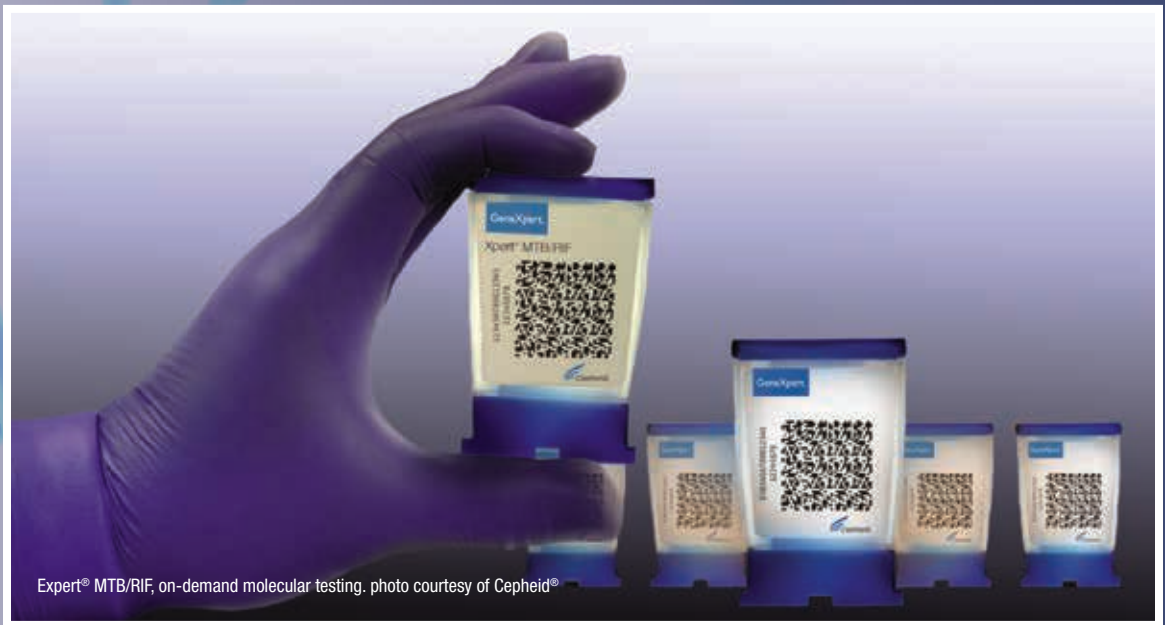
Considerations for Infection Control

CDC recommends airborne infection isolation precautions for patients with suspected TB disease of the lungs, airway, or larynx. Precautions may be discontinued when contagious TB disease is considered unlikely and either:[4]

- Another diagnosis is made that explains the clinical syndrome, or
- Patient has three consecutive negative sputum smears by microscopy, NAA (including Xpert MTB/RIF assay) or a combination of the two. The New Jersey Administrative Code (§8:57-5.7) allows for the discontinuation of [TB] infection control measures and discharge of a patient with smear(s) positive for AFB in the presence of a NAA test negative for MTBC

For patients with a diagnosis of TB, the decision to discontinue isolation precautions should be based on microscopy (i.e., three consecutive negative smears) and other clinical criteria.

Updated Recommendations for Tuberculosis Testing



Expert® MTB/RIF, on-demand molecular testing. photo courtesy of Cepheid®

The Xpert MTB/RIF is the only NAA test that also detects rifampicin resistance-conferring mutations directly from sputum, in an assay providing results within two hours.[4]

Until recently, there were two types of NAA tests approved by the Food and Drug Administration (FDA): the Amplified Mycobacterium tuberculosis Direct Test and the Amplicor Mycobacterium tuberculosis Test. In 2011 the World Health Organization supported widespread use of a third NAA test to support TB diagnosis: the Xpert MTB/RIF. In August 2013, the FDA permitted its marketing in the United States. The Xpert MTB/RIF is the only NAA test that also detects rifampicin resistance-conferring mutations directly from sputum, in an assay providing results within two hours.[4] It is also the only NAA test that is cartridge-based and fully automated; cartridges are pre-loaded with all reagents necessary for sample processing, DNA extraction, amplification, and laser detection of target amplicon binding to the molecular beacons. It was developed through partnership of Cepheid, Inc, the Foundation for Innovative New Diagnostics (FIND), with financial support from the National Institutes of Health, and technical support from the University of Medicine and Dentistry of New Jersey (now Rutgers, The State University of New Jersey).[6]

Sensitivity and specificity of the Xpert MTB/RIF assay for detection of MTBC appear to be comparable with other FDA-approved NAA assays, although direct comparison studies have not been performed due to limited use. Sensitivity of detection of Rifampin resistance was 95% and specificity 99% in a multicenter study using archived and prospective specimens from subjects aged ≥18 years suspected of having TB who had 0–3 days of antituberculous treatment.[4]

Providers and laboratories need to ensure that specimens are available for other recommended mycobacteriological testing. Rifampin resistance most often coexists with isoniazid (INH) resistance; TB that is resistant to both drugs is considered multidrug-resistant (MDR) TB. The prevalence of rifampim resistance is low in the United States (about 1.8% of TB cases); a positive result indicating a mutation in the rpoB gene of MTBC should be confirmed by rapid DNA sequencing for prompt reassessment of the treatment regimen and followed by growth-based drug susceptibility testing.[4]

This article is for informational purposes and does not constitute or imply an endorsement by the New Jersey Department of Health.

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NEW JERSEY AIDSLine December 2013

CDC Evaluating New HIV Diagnostic Testing Algorithm

Eric Musser and Virginia Allread

Overview

Since the release of the first testing recommendations for diagnosis of HIV infection by the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL) in 1989, HIV testing technology has changed significantly with the introduction of new immunoassays, point-of-care rapid tests and molecular detection techniques.

Although revisions of the HIV testing guidelines have occurred periodically, testing recommendations have remained mostly unchanged since its introduction in 1989, sparking a need for updates.[1] The current HIV diagnostic algorithm consists of:[2]

1. Repeatedly reactive immunoassay (IA). Note: until recently the IA was typically referred to as an "antibody test". Antibody test is now inaccurate as fourth generation IA detect both antigen and antibody (see below).
2. Followed by a supplemental test, such as the Western blot (WB) or indirect immunofluorescence assay (IFA)

Early IAs—first and second generation—detected only immunoglobulin G (IgG)-class antibodies. Most laboratories now use either:

- Third-generation IAs that detect both immunoglobulin M-class and IgG-class antibodies or
- Fourth-generation combination antigen/antibody IAs that detect both classes of antibody (HIV-1 or HIV-2) and also p24 antigen (a major core protein of HIV). The p24 antigen can be detected early, before antibody appears, allowing the fourth-generation IAs to identify some HIV infections in the acute phase.

There are two problems with the current diagnostic algorithms:

1. If third- or fourth-generation IA is used, the IA detects HIV infection earlier than supplemental tests. Reactive IA results and negative supplemental test results (i.e., discordant results) very early in the course of HIV infection have been incorrectly interpreted as negative. This error can potentially lead to late diagnosis and further HIV transmission within the community.
2. If a third generation IA is used, the algorithm cannot detect acute infections and misclassifies approximately 60% of HIV-2 infections as HIV-1, based on HIV-1 WB results.[2] (The HIV-1 WB is a complex assay, proteins from HIV-2 migrate along the WB and are sometimes misidentified.)

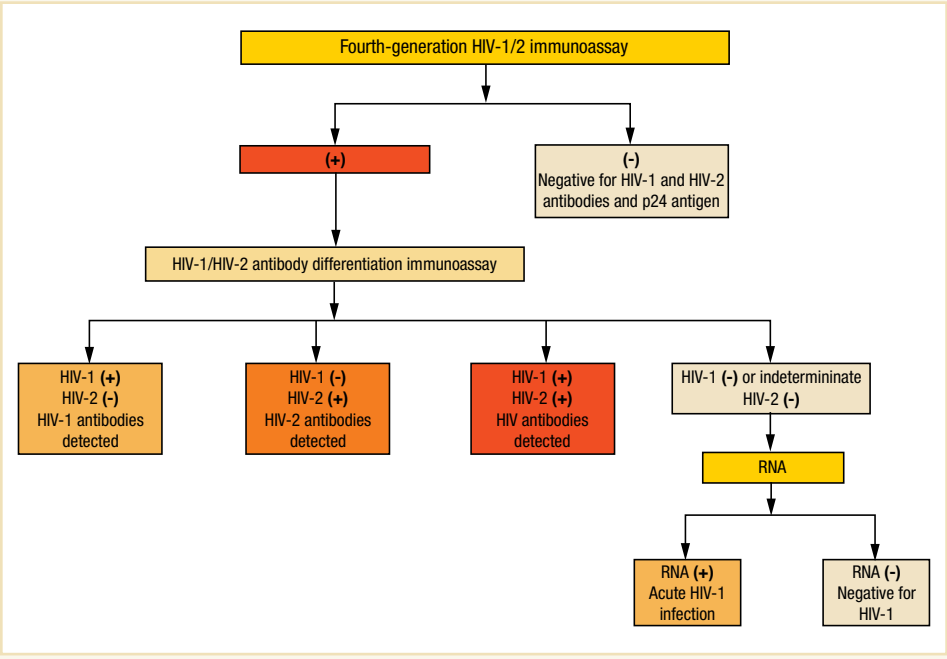
CDC recently published the results of an evaluation of a new HIV testing algorithm.[2] The new diagnostic algorithm replaces the WB with an HIV-1/HIV-2 antibody differentiation assay (the Multispot HIV-1/HIV-2 rapid test, which was approved by the Food and Drug Administration (FDA) in March 2013) as a supplemental test. The new algorithm also includes an additional step: an RNA test for specimens that are discordant, i.e., reactive by IA but negative by the supplemental test.

Currently, only one RNA assay, the Aptima HIV-1 RNA Qualitative Assay, is FDA-approved for HIV diagnosis, but it is available in far fewer laboratories than quantitative HIV-1 (viral load) RNA assays. To facilitate prompt diagnosis of acute HIV infection when faced with discordant screening and supplemental test results, clinicians can order a viral load test to differentiate acute HIV-1 infection from false-positive IA results.

4th generation IAs

Laboratory-based fourth generation IAs have been available since June 2010 when the FDA approved Abbott's Architect HIV Ag/Ab Combo Assay. Subsequently (July 2011) Bio-Rad's GS HIV Combo Ag/Ab EIA was also approved. On August 9, 2013 the FDA approved a new point-of care assay, Alere Inc.'s, 4th-generation rapid IA, Determine™ HIV 1/2 Ag/Ab Combo. While Abbott and Bio-Rad's assays require large analyzers, Determine™ Combo is unique in that it is the first of its kind not to need large immunoassay analyzers for diagnostic results. Similar to the rapid tests cur-

New CDC HIV diagnostic testing algorithm under evaluation



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rently in use, the Determine™ Combo can be conducted at point-of-care, provides results in 20–30 minutes and requires minimal training and no laboratory equipment. It can detect antigen 12–26 days after infection.[3] According to the FDA, "the test can be used by trained professionals in outreach settings to identify HIV-infected individuals who might not be able to be tested in traditional health settings."[4] The initial FDA approval of Determine is restricted to Clinical Laboratory Improvement Amendments (CLIA) Moderate Complexity laboratories such as those found in many healthcare facilities, but the company is seeking CLIA waiver which will increase its availability and usefulness in screening sites nationally.

The interval between the appearance of HIV RNA in plasma and the detection of HIV-specific antibodies, often referred to as the "window period" contributes disproportionately to HIV transmission because infection is not detected by traditional antibody assays (so individuals do not know they are infected, even if tested) and those who are in the window period are highly infectious. This period of high levels of viremia is also referred to as acute HIV infection. Detection of the p24 antigen can close the window period by about 5 days.[5]

Determine Combo Rapid HIV 1/2 Ag/Ab Test

- CLIA moderate complexity
- Distinguishes Ag from Ab
- Whole blood, serum plasma
- FDA-approved August 2013

Advantages of the new algorithm

In the CDC evaluation,[2] the ongoing Screening Targeted Populations to Interrupt On-going Chains of HIV Transmission with Enhanced Partner Notification (STOP) study, with sites in New York, North Carolina and California, identified 99 cases with reactive IA and negative supplemental test results (i.e., discordant test results) between September 2011 and September 2012. Of these 99 discordant results 55 (55.6%) were acute HIV infections. Between July 2011 and February 2013 an HIV screening program at a Phoenix, Arizona emergency department (ED) identified 37 undiagnosed HIV infections. Of these 37, 12 (32.4%) were acute HIV infections. The high percentage of HIV infections that were acute among these emergency department patients was unexpected; however, consistent with observations that 50%–90% of persons with acute HIV infection develop symptoms that prompt them to seek medical care. This finding suggests that acute HIV infection in persons who seek care for their nonspecific symptoms in urgent-care venues might go undiagnosed unless HIV screening is conducted with fourth-generation HIV IAs.

CDC is still developing the new HIV diagnostic algorithm. In the meanwhile, they recommend that clinicians remain vigilant for discordant IA and supplemental test results and either order an HIV-1 (viral load) RNA assay or obtain follow-up HIV testing (in 2–4 weeks) to accurately determine whether HIV infection is present. ❖

This article is for informational purposes and does not constitute or imply an endorsement by the New Jersey Department of Health.

The authors gratefully acknowledge contributions from Eugene Martin and Joanne Phillips.

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Prenatal and Newborn HIV Testing, Legal Trends Over Two Decades

By Melissa Friedman

Introduction

CDC estimates that over 223,000 adult and adolescent females in the United States have been diagnosed with HIV infection, not including approximately 49,000 women who are HIV infected but not yet diagnosed.[1] Any pregnant or breastfeeding woman with HIV—or who acquires HIV while pregnant or breastfeeding—can transmit the virus to her infant. This is particularly an issue if her infection is not diagnosed or if she is not in care. The prevalence of HIV, in conjunction with the fact that the disease is presently incurable, places jurisdictions—including states such as New Jersey—in a precarious position as the guardian of women's rights, children's rights, public health and safety. The question of what states **should** do, and what they **can** do, to prevent the transmission of HIV brings to the forefront issues regarding their role and how a state is to balance competing interests, particularly within the realm of the family. This article is a discussion of a state's power to intervene in the parent-child relationship. More specifically, this article will trace the development of maternal-fetal testing laws on the federal and state levels.

The prevalence of HIV, in conjunction with the fact that the disease is presently incurable, places jurisdictions—including states such as New Jersey—in a precarious position as the guardian of women's rights, children's rights, public health and safety.

Background

In order to understand the following legal arguments, a cursory overview of the science behind HIV transmission from mother-to-child is essential. The primary periods of transmission are during gestation, labor and delivery, and postpartum as a result of breastfeeding. Without intervention, about 22.5% of formula fed infants born to women with HIV will acquire HIV from their mothers—about 5.5% in utero and 18% intrapartum.[2] Breastfeeding accounts for an additional 14–29% of the total cases transmitted.[3] Transmission depends primarily on maternal viral load—the higher the viral load the more likely is transmission.[4] It is significantly more effective to prevent perinatal transmission of HIV with interventions initiated prenatally than postnatally. If maternal HIV is diagnosed prenatally, the mother provided with antiretroviral drugs and cesarean delivery (if indicated), and breastfeeding is avoided, 98–99% of transmissions can be prevented;[5,6] while only 90% can be prevented if the mother is diagnosed and treated with ARVs around the time of birth.[7]

If a mother is HIV-positive, her baby will test HIV antibody positive at birth, and for the first 12–18 months of life,[8] whether infected or not. By 18 months of age, the uninfected child will test HIV antibody negative. Therefore, an HIV test of a newborn is effectively an HIV test of the mother.[4]

Presently the medical and legal communities have quite literally "split the baby" in regard to HIV testing and maternal-fetal transmission by staking out a statutory middle ground between protecting women's right to privacy and protecting children from HIV infection. For example, the New Jersey testing statute mandates opt-out testing during the first and third trimester with mandatory HIV testing for newborns if the mother's HIV status is unknown at birth. Thus, women's rights are not fully protected, as a test of a newborn reveals the status of the mother, and the health of the child is not fully protected as transmission rates are reduced only 90% after birth,[7] as opposed to the 98–99% reduction possible prenatally.[9]

The evolution of transmission prevention statutes 1981–today

HIV was first recognized in 1981,[10] and the first reported cases of prenatal HIV infection appeared in 1982.[11] By 1985, the Centers for Disease Control and Prevention (CDC) released its first official recommendations on prevention of prenatal HIV infection. CDC advised HIV-infected women to consider delaying pregnancy and avoid breastfeeding until more was known.[12] As a response to this, counselors would recommend that HIV-infected women avoid pregnancy for now, or consider abortion or sterilization.[13]

At the outset, HIV was considered primarily an issue of gay and drug-using populations.[14] However, the issues surrounding maternal-fetal transmission came into prominence between 1985 and 1990 when the incidence of AIDS in women nearly doubled,[15] increasing 34% in one year (1989–90) alone.[16] In 1988, as a response to the increasing number of female HIV infections[8] and the subsequent increase in HIV infected newborns, CDC began a nationwide program of blind testing of newborns in forty-five states to track HIV prevalence.[17] CDC also began recommending a targeted counseling and testing regime for only high-risk women and those women from high-prevalence geographic areas. Simultaneously, a randomized, double-blind placebo controlled study entitled "Pediatric AIDS Clinical Trials Group (PACTG) protocol 076" was designed and implemented to determine the impact of antiretroviral drugs on transmission.[18]

The enormous increase in female and prenatal HIV infections also spurred a flurry of legislative action. On the federal level, the Ryan White Care Act was enacted on August 18, 1990. The Ryan White HIV/AIDS Program remains an important source of funding for HIV-related care: it is currently funded at $2.1 billion and provides HIV-related services to more than half a million people each year.[19] On the local level, the first mandatory testing bill, the Baby AIDS Bill,[20] was proposed in the New York State legislature in the early 1990s. At the time, New York accounted for approximately a quarter of the country's pediatric HIV infections, with more than 87% of those reported in New York City.[21] Around this time approximately 855 children per year were contracting HIV through maternal-fetal transmission in the U.S.[22]

At the same time as New York's legislative activity, the foster care agency—the Association to Benefit Children (ABC)—spurred a child welfare debate regarding HIV infection. ABC began advocating for mandatory testing of newborns in response to the difficulties foster parents experienced in authorizing their foster children for testing without the consent of their natural parents.[20]

The political debate regarding mandatory versus voluntary prenatal and newborn testing took on a national dimension with the release of the PACTG 076 results in 1994.[23] The results of this clinical trial showed that using zidovudine (AZT) during pregnancy, labor and delivery, and the first few weeks of a newborn's life could decrease the risk of mother-to-child HIV transmission from 25% to 8%, a 67% decrease.[24] The results were so remarkable that the clinical trial was stopped early as health officials deemed it unethical to provide some women with placebo when transmission could be prevented, and all the clinical trial participants were placed on AZT.[20] In response, CDC also halted its blind newborn surveillance testing.[17] CDC proposed new guidelines advising universal counseling and voluntary HIV testing of pregnant women in lieu of the previous targeted approach[20] as well as the use of AZT to reduce perinatal transmission of HIV.[25]

In 1996 the federal government also reacted to the PACTG 076 study by amending the Ryan White legislation[26] and requiring the Secretary of Health and Human Services (HHS) to determine whether, by September 1998, newborn testing had become routine. If so, states had eighteen months to show they had reduced the rate of reported pediatric AIDS cases by 50% compared to 1993 data or have knowledge of HIV status of 95% of pregnant of women who obtained prenatal care at least twice prior to 34 weeks.[26] If a state could not meet this criterion, they would lose funding.[27] While the federal government did not go as far as to mandate testing, they created a very strong incentive scheme for aggressive testing measures.

As public awareness grew in the mid to late nineties, the courts for the first time became a vehicle for mandating newborn HIV testing. ABC, with support from Netti Mayerson, the New York State Assemblywoman who proposed the Baby AIDS Bill, brought suit against the governor of New York, on behalf of "Baby Girl Doe" seeking routine HIV testing for all newborns and treatment and counseling for all HIV positive infants, mothers and other family members. In September 1995 the suit was settled, calling for newborn testing with consent and mandatory testing if the physician perceived an emergency (at the time, confidentiality legislation prevented universal mandatory testing). The momentum gained from this decision, combined with the changes to the federal Ryan White legislation propelled the New York Baby AIDS bill to be passed in 1996 and signed in 1997.[20] At the same time, similar legislation was also introduced in Illinois, Michigan, Pennsylvania and Florida among other states that pushed mandatory testing of newborns or pregnant women.[27]

Opt-out versus Opt-in testing

- **Opt-out testing:** testing routinely, i.e., after notifying the patient that the test is normally performed. Assent is assumed unless the patient declines or defers testing.
- **Opt-in testing:** testing only when explicit permission from the patient is given.

Most standard blood tests are conducted as opt-out tests. CDC recommends opt-out HIV testing policies in health care settings.

In the late 1990s the legislative trend was opt-in testing for pregnant women and newborns. One study indicated that 87% of reporting jurisdictions (43 states, two territories) had policies on counseling and testing of pregnant women, the vast majority of which required voluntary testing with informed consent.[20] This began to change in 1999, when the Institute of Medicine, following an evaluation of perinatal transmission of HIV funded and mandated by the Ryan White legislation, concluded that, in light of advances in antiretroviral therapy and potential to reduce perinatal HIV transmission, "the United States should adopt a national policy of universal HIV testing, with patient notification as a routine component of prenatal care."[28] Around the same time, viral load testing became available, making transmission easier to prevent by providing laboratory guidance for the effectiveness of antiretroviral therapy and the potential need for a caesarean section to reduce the risk of transmission.

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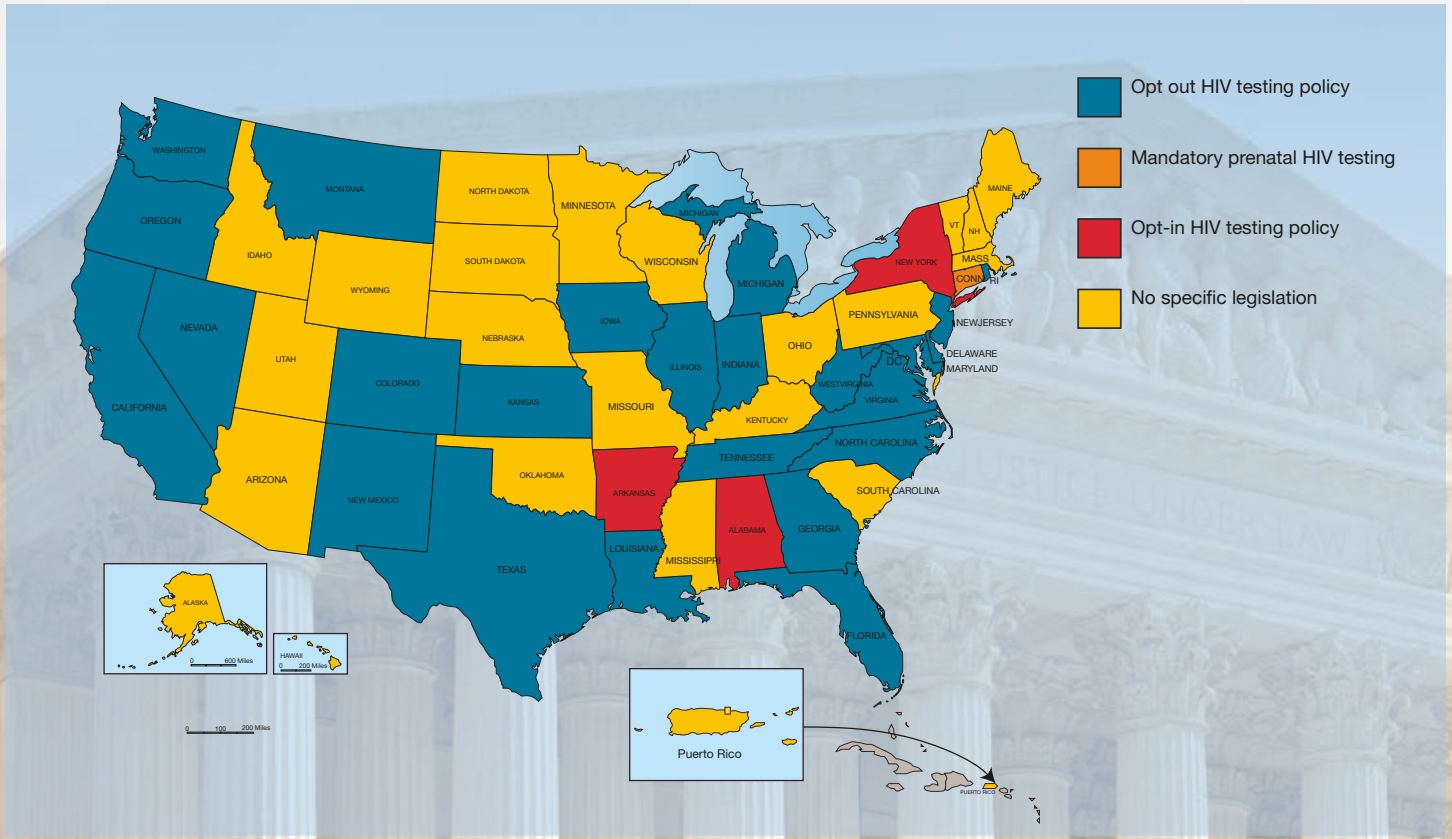

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The Ryan White legislation was subsequently amended again in 2000 to give preferential funding to states that most aggressively pursued transmission reduction, with the most money going towards those with mandatory newborn testing policies.[8] Subsequently, in 2001 CDC recommended routine perinatal testing with simplified informed consent, indicating a stronger position on testing[28] and the American College of Obstetrics and Gynecology launched a campaign for universal opt-out HIV screening of all pregnant women.[28] By 2002, 17 states had prenatal testing statutes: 11 offered the opt-in model, and 6 the opt-out. Four states had also developed specific newborn statutes: Connecticut and New York mandated testing if the mother's HIV status was unknown at birth, Rhode Island required informed consent, and Indiana permitted newborn testing.

Current statutes

In 2006, CDC released their most recent (to date) recommendations, advocating the testing of pregnant women as early in pregnancy as possible with repeat testing in the third trimester in high prevalence jurisdictions—which included New Jersey—and rapid HIV testing in labor and delivery and for newborns if the mother was not tested or not retested in 3rd trimester.[28] These recommendations have become a model for state legislation, and many states mandate testing specifically in accordance with CDC recommendations. Currently:

- 23 states have no specific legislation
- 3 states have opt-in prenatal testing (including New York, which has mandatory newborn testing if the mother's HIV status is unknown at birth)
- 24 states—including New Jersey—have opt-out testing policies (with eight of those mandating newborn testing if the mother's HIV status is unknown at birth)
- 1 state, Connecticut, has mandatory prenatal HIV testing

The shift towards mandatory newborn testing over the last ten years demonstrates a trend towards more aggressive HIV testing measures.[30] These measures have resulted in a 93% decline in maternal-fetal transmission cases, from a peak of 1,650 in 1991 to approximately 127 in 2011.[22, 31]

This article was edited by Virginia Allread with contributions from Joanne Phillips and Carolyn Burr. ❖

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The US Food and Drug Administration (FDA) Approves New HIV Drug: Tivicay

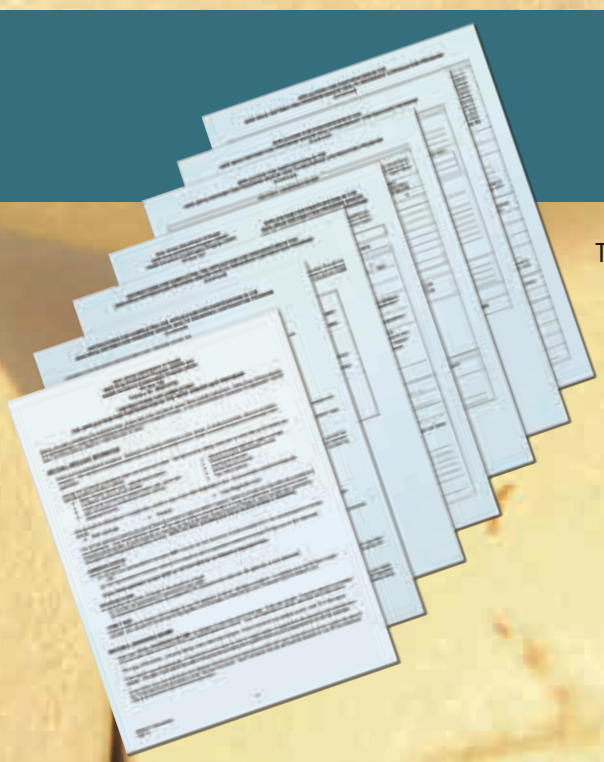
Priyanka R. Oza

On Monday, August 12, 2013, the FDA approved, Tivicay, a new drug for the treatment of HIV infection. Generically known as Dolutegravir, it belongs to a class of drugs known as integrase inhibitors that interferes with one of the enzymes necessary for HIV to multiply. Tivicay is owned by ViiV Healthcare, and Shionogi & Co Ltd.

According to FDA guidelines, Tivicay can be used to initiate treatment in patients new to treatment, as well as patients already on other treatment regimes. Although Tivicay can be given to adults who have been treated with other integrase strand transfer inhibitors, it has been approved only for use in children who have not received treatment with other integrase inhibitors, who are at least 12 years of age and weigh at least 12 kg. Side effects include: insomnia and headache. Serious side effects include: allergic reactions and abnormal liver function in patients infected with hepatitis B or C.

The AIDS Drug Distribution Program (ADDP) provides medications to low income individuals that have no other source of income to pay for drugs such as Tivicay. The ADDP includes all FDA approved HIV/AIDS medications on its formulary. To qualify for ADDP, the patient needs to be a New Jersey resident, 30 days prior to date of application, with an annual income that must not exceed 500% of the federal poverty level. Patients receiving other forms of reimbursement through private insurance are not eligible for ADDP, unless they have received maximum benefits under their plan and are still in need of further assistance. A podcast describing ADDP and the application process is available at: *http://hpcpsdi.rutgers.edu/training/main.php.*

To apply call 1-877-613-4533 or visit: *http://www.state.nj.us/health/aids/freemeds.shtml#addp*



Dolutegravir, it belongs to a class of drugs known as integrase inhibitors that interferes with one of the enzymes necessary for HIV to multiply.

This article is for informational purposes and does not constitute or imply an endorsement by the New Jersey Department of Health or the ADDP. ❖

U.S. Food and Drug Administration. FDA Approves New Drug to Treat HIV Infection. August 12, 2013. Available at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm364744.htm

State of New Jersey, Department of Health, Free Medications for Individuals with HIV/AIDS. 2013. Available at: http://www.state.nj.us/health/aids/freemeds.shtml#addp

New Virulent HIV Strain Identified by Russian Scientists

A researcher examines a sample at Russia's State Research Center of Virology and Biotechnology (Vector) in Koltsovo, near Novosibirsk. (file photo) http://www.rferl.org/content/russia-hiv-new-strain-aids/25139509.html

"Russia has experienced the fastest-spreading HIV/AIDS epidemics in any one country in history, but there remains a lack of effective preventive measures to slow it down—in large measure because the people most affected are also the country's most reviled," wrote Gregory Gilderman of the Pulitzer Center.

Russian scientists believe they have discovered a new, more easily transmitted type of HIV. The new strain was first identified in 2006 and known as 02_AG/A. HIV is categorized into two groups: HIV-1, which is more infectious, and HIV-2. Researchers believe the 02_AG/A strain, a subtype of HIV-1, is transmitted more easily than other strains of the virus. It is thought to account for more than 50% of new HIV infections in Siberia and is being transmitted at a "rapid rate" in Russia, Chechnya, Kyrgyzstan, and Kazakhstan.

Worldwide, new HIV infection numbers dropped by 30% since 2001, but Eastern Europe and Central Asia is the only region where HIV prevalence clearly remains on the rise. The number of people living with HIV has almost tripled since 2000, with the majority of cases located in Russia. Approximately 1 million of Russia's 143 million residents are HIV-positive (by comparison, the United States has a slightly higher prevalence of 1.1 million but more than twice the population: 308.7 million according to 2010 census). A rapid rise in HIV infections among people who inject drugs at the turn of the century caused the epidemic in this region to surge.

The 02_AG/A subtype of the virus was first seen in the city of Novosibirsk in 2006 and is thought to be the most virulent subtype in Russia. According to Russia's Federal AIDS Center, the number of infected people in Novosibirsk, Russia, rose from 2,000 in 2007 to 15,000 in 2012. "Russia has experienced the fastest-spreading HIV/AIDS epidemics in any one country in history, but there remains a lack of effective preventive measures to slow it down—in large measure because the people most affected are also the country's most reviled," wrote Gregory Gilderman of the Pulitzer Center. He noted that the empowerment of women in particular, "is vital to reversing the HIV/AIDS epidemic." The World Bank estimated that by 2020, nearly 21,000 Russians per month could die because of HIV. ❖

Lecia Bushak, NPIN, News. *New Virulent HIV Strain Spreading Rapidly Through Siberia Identified by Russian Scientists; Accounts for 50 Percent of New Infections.* October 19, 2013. Available at: http://www.cdcnpin.org/scripts/display/NewsDisplay.asp?NewsNbr=62219

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Background photo: Novossibirsk Station, Russia – Credit: Tensaibuta – http://farm4.staticflickr.com/. The subtype, called 02_AG/A, was first reported in Russia's Siberian city of Novossibirsk in 2006 and is now responsible for more than 50 percent of new HIV infections in the region as reported by the Moscow News.

NEW JERSEY December 2013

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65 Bergen Street, 8th floor
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New Jersey AIDSLine is published by
FXB Center, School of Nursing, Rutgers, The State University of New Jersey with the New Jersey Department of Health, Division of HIV, STD and TB Services (NJDOH-DHSTS) through a Memorandum of Agreement titled "Education and Training for Physicians and Other Healthcare Professionals in the Diagnosis and Treatment of HIV/AIDS". Continuing education credits are offered by the Rutgers Center for Continuing & Outreach Education, http://ccoe.rbhs.rutgers.edu/

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AIDSinfo: a service of the U.S. Department of Health and Human Services, offers access to the latest, federally approved HIV/AIDS medical practice guidelines, HIV treatment and prevention clinical trials, and other research information. http://www.aidsinfo.nih.gov/

AIDS InfoNet: HIV treatment fact sheets in English and 10 other languages. www.aidsinfonet.org

ClinicalTrials.gov: a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. http://clinicaltrials.gov

Centers for Disease Control and Prevention (CDC): Key HIV/AIDS resources. http://www.cdc.gov/hiv/default.html

Health Resources and Services Administration (HRSA): http://www.hrsa.gov and http://hab.hrsa.gov

FDA MedWatch: (800) FDA-1088; Subscribe to e-bulletin: www.fda.gov/medwatch/elist.htm

HealthHIV: Advances effective prevention, care and support for people living with, or at risk for, HIV/AIDS by providing education, capacity building, health services research, and advocacy. http://www.healthhiv.org/index.php

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